



Clinical trial results:

A Phase 1/2 First-in-Human Study of BMS-986249 Alone and in Combination with Nivolumab in Advanced Solid Tumors

Summary

EudraCT number	2018-000416-21
Trial protocol	ES DE PL FI IT RO
Global end of trial date	07 November 2024

Results information

Result version number	v1 (current)
This version publication date	22 November 2025
First version publication date	22 November 2025

Trial information

Trial identification

Sponsor protocol code	CA030-001
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, mg-gsm-ct@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, mg-gsm-ct@bms.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	07 November 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the safety, tolerability, and DLTs and to determine the MTD/RP2D of BMS-986249 administered as monotherapy and in combination with nivolumab in participants with advanced solid tumors (Parts 1A and 1B)

To evaluate the preliminary safety and tolerability of BMS-986249 in combination with nivolumab (Arm C and Arm F) relative to ipilimumab in combination with nivolumab (Arm D) in participants with previously untreated, unresectable or metastatic melanoma

To evaluate the preliminary efficacy of BMS- 986249 in combination with nivolumab (Arm C and Arm F) relative to historic nivolumab monotherapy data in participants with previously untreated, unresectable or metastatic melanoma

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 December 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 4
Country: Number of subjects enrolled	Germany: 30
Country: Number of subjects enrolled	Italy: 24
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Spain: 41
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	United States: 90
Country: Number of subjects enrolled	Argentina: 35
Country: Number of subjects enrolled	Australia: 13
Country: Number of subjects enrolled	Chile: 97
Country: Number of subjects enrolled	Romania: 18
Worldwide total number of subjects	356
EEA total number of subjects	119

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)	221
From 65 to 84 years	135
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

356 subjects enrolled and treated

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
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Arm title	Part 1A: BMS-986249 240 mg Monotherapy
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Arm description:

BMS-986249 240 mg IV every 4 weeks (Q4W), up to 2 years

Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160mg/vial (40mg/mL)

Arm title	Part 1A: BMS-986249 800 mg Monotherapy
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Arm description:

BMS-986249 800 mg IV every 4 weeks (Q4W), up to 2 years

Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160mg/vial (40mg/mL)

Arm title	Part 1A: BMS-986249 1600 mg Monotherapy
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Arm description:

BMS-986249 1600 mg IV every 4 weeks (Q4W), up to 2 years

Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160mg/vial (40mg/mL)

Arm title	Part 1A: BMS-986249 2400 mg Monotherapy
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Arm description:	
BMS-986249 2400 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	
Arm title	Part 1A: BMS-986249 1600 mg Q8W Monotherapy
Arm description:	
BMS-986249 1600 mg IV every 8 weeks (Q8W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	
Arm title	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination
Arm description:	
BMS-986249 240 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	
Arm title	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination
Arm description:	
BMS-986249 800 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
100mg/vial (10mg/mL)	
Arm title	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Arm description:	
BMS-986249 1200 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	
Arm title	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination
Arm description:	
BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
100mg/vial (10mg/mL)	
Arm title	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination
Arm description:	
BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 160mg/vial (40mg/mL)	
Arm title	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination
Arm description: BMS-986249 1600 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 160mg/vial (40mg/mL)	
Arm title	Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W
Arm description: BMS-986249 240 mg IV every 3 weeks (Q3W) + nivolumab 360 mg IV every 3 weeks (Q3W) (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) (maintenance), up to 2 years.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 160mg/vial (40mg/mL)	

Arm title	Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W
Arm description: BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 160mg/vial (40mg/mL)	
Arm title	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Arm description: BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 160mg/vial (40mg/mL)	
Arm title	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W
Arm description: Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.	
Arm type	Experimental
Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 50mg/vial (5mg/mL)	

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Arm title	Part 2A Arm E: Nivo 480 mg Q4W Monotherapy
Arm description: Nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Arm title	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W
Arm description: BMS-986249 600 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years.	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 160mg/vial (40mg/mL)	
Arm title	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
Arm description: BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg/vial (10mg/mL)	
Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
160mg/vial (40mg/mL)	

Arm title	Part 2B: Cohort 2 (Metastatic CRPC)
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Arm description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100mg/vial (10mg/mL)

Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160mg/vial (40mg/mL)

Arm title	Part 2B: Cohort 3 (Unresectable TNBC)
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Arm description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100mg/vial (10mg/mL)

Investigational medicinal product name	BMS-986249
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

160mg/vial (40mg/mL)

Number of subjects in period 1	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy
Started	6	11	10
Treated	6	11	10
Completed	0	0	0
Not completed	6	11	10
Adverse event, serious fatal	-	-	-
Disease progression	6	8	5
Participant withdrew consent	-	1	1
Study drug toxicity	-	1	4
Randomized but not treated	-	-	-
Participant no longer meets study criteria	-	-	-
Adverse event unrelated to study drug	-	-	-
Other reasons	-	-	-
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	-	1	-

Number of subjects in period 1	Part 1A: BMS-986249 2400 mg Monotherapy	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination
Started	1	11	12
Treated	1	11	12
Completed	0	0	0
Not completed	1	11	12
Adverse event, serious fatal	-	-	-
Disease progression	1	9	9
Participant withdrew consent	-	-	-
Study drug toxicity	-	1	2
Randomized but not treated	-	-	-
Participant no longer meets study criteria	-	-	-
Adverse event unrelated to study drug	-	-	-
Other reasons	-	-	-
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	-	1	1

Number of subjects in period 1	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination
Started	11	9	13
Treated	11	9	13

Completed	0	0	0
Not completed	11	9	13
Adverse event, serious fatal	-	-	-
Disease progression	4	6	10
Participant withdrew consent	1	1	1
Study drug toxicity	4	2	2
Randomized but not treated	-	-	-
Participant no longer meets study criteria	-	-	-
Adverse event unrelated to study drug	1	-	-
Other reasons	-	-	-
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	1	-	-

Number of subjects in period 1	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W
Started	9	10	3
Treated	9	10	3
Completed	1	0	0
Not completed	8	10	3
Adverse event, serious fatal	-	-	-
Disease progression	7	4	1
Participant withdrew consent	-	-	1
Study drug toxicity	-	6	1
Randomized but not treated	-	-	-
Participant no longer meets study criteria	-	-	-
Adverse event unrelated to study drug	1	-	-
Other reasons	-	-	-
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	-	-	-

Number of subjects in period 1	Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W
Started	3	58	59
Treated	3	57	58
Completed	0	6	7
Not completed	3	52	52
Adverse event, serious fatal	-	1	-
Disease progression	1	25	22
Participant withdrew consent	-	-	3

Study drug toxicity	2	19	19
Randomized but not treated	-	1	1
Participant no longer meets study criteria	-	-	2
Adverse event unrelated to study drug	-	4	2
Other reasons	-	1	2
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	-	1	1

Number of subjects in period 1	Part 2A Arm E: Nivo 480 mg Q4W Monotherapy	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
Started	3	36	5
Treated	3	36	5
Completed	1	2	0
Not completed	2	34	5
Adverse event, serious fatal	-	-	-
Disease progression	2	10	1
Participant withdrew consent	-	1	-
Study drug toxicity	-	18	3
Randomized but not treated	-	-	-
Participant no longer meets study criteria	-	2	-
Adverse event unrelated to study drug	-	2	1
Other reasons	-	1	-
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	-	-	-

Number of subjects in period 1	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)
Started	41	45
Treated	41	45
Completed	1	3
Not completed	40	42
Adverse event, serious fatal	1	-
Disease progression	18	28
Participant withdrew consent	4	2
Study drug toxicity	11	7
Randomized but not treated	-	-
Participant no longer meets study criteria	-	-
Adverse event unrelated to study drug	3	2
Other reasons	-	2

Lost to follow-up	2	1
Participant request to discontinue study treatment	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Part 1A: BMS-986249 240 mg Monotherapy
Reporting group description: BMS-986249 240 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 800 mg Monotherapy
Reporting group description: BMS-986249 800 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 1600 mg Monotherapy
Reporting group description: BMS-986249 1600 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 2400 mg Monotherapy
Reporting group description: BMS-986249 2400 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 1600 mg Q8W Monotherapy
Reporting group description: BMS-986249 1600 mg IV every 8 weeks (Q8W), up to 2 years	
Reporting group title	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination
Reporting group description: BMS-986249 240 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Reporting group title	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination
Reporting group description: BMS-986249 800 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Reporting group title	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Reporting group description: BMS-986249 1200 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Reporting group title	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination
Reporting group description: BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination
Reporting group description: BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination
Reporting group description: BMS-986249 1600 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W
Reporting group description: BMS-986249 240 mg IV every 3 weeks (Q3W) + nivolumab 360 mg IV every 3 weeks (Q3W) (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) (maintenance), up to 2 years.	
Reporting group title	Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W
Reporting group description: BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Reporting group description: BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W

Reporting group description:

Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

Reporting group title	Part 2A Arm E: Nivo 480 mg Q4W Monotherapy
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Reporting group description:

Nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

Reporting group title	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986249 600 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years.

Reporting group title	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
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Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years

Reporting group title	Part 2B: Cohort 2 (Metastatic CRPC)
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Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Reporting group title	Part 2B: Cohort 3 (Unresectable TNBC)
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Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Reporting group values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy
Number of subjects	6	11	10
Age categorical			
Units: Subjects			
Adults (18-64 years)	4	6	5
From 65-84 years	2	5	5
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	54.0	64.8	60.4
standard deviation	± 18.9	± 7.5	± 10.2
Sex: Female, Male			
Units: Participants			
Female	3	8	8
Male	3	3	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	1
White	4	11	7
More than one race	0	0	0
Unknown or Not Reported	1	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	1	0

Not Hispanic or Latino	5	10	8
Unknown or Not Reported	0	0	2

Reporting group values	Part 1A: BMS-986249 2400 mg Monotherapy	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination
Number of subjects	1	11	12
Age categorical Units: Subjects			
Adults (18-64 years)	1	6	10
From 65-84 years	0	5	2
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	64	60.3	56.3
standard deviation	± 99999	± 11.6	± 8.8
Sex: Female, Male Units: Participants			
Female	0	7	9
Male	1	4	3
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	0
White	1	8	11
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	2	2
Not Hispanic or Latino	0	7	10
Unknown or Not Reported	0	2	0

Reporting group values	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination
Number of subjects	11	9	13
Age categorical Units: Subjects			
Adults (18-64 years)	10	5	11
From 65-84 years	1	4	2
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	53.9	61.4	55.3
standard deviation	± 12.4	± 11.2	± 11.4

Sex: Female, Male			
Units: Participants			
Female	4	1	4
Male	7	8	9
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	2
White	11	6	9
More than one race	0	0	0
Unknown or Not Reported	0	2	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	10	6	10
Unknown or Not Reported	0	3	2

Reporting group values	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W
Number of subjects	9	10	3
Age categorical			
Units: Subjects			
Adults (18-64 years)	7	6	1
From 65-84 years	2	4	2
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	59.0	60.1	60.7
standard deviation	± 8.0	± 9.9	± 13.6
Sex: Female, Male			
Units: Participants			
Female	5	4	1
Male	4	6	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	9	10	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	2	0
Not Hispanic or Latino	8	6	3
Unknown or Not Reported	1	2	0

Reporting group values	Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W
Number of subjects	3	58	59
Age categorical Units: Subjects			
Adults (18-64 years)	0	34	39
From 65-84 years	3	24	20
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	73.3	61.4	57.3
standard deviation	± 7.6	± 14.7	± 13.8
Sex: Female, Male Units: Participants			
Female	1	22	27
Male	2	36	32
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	3	57	57
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	7	11
Not Hispanic or Latino	1	11	8
Unknown or Not Reported	1	40	40

Reporting group values	Part 2A Arm E: Nivo 480 mg Q4W Monotherapy	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
Number of subjects	3	36	5
Age categorical Units: Subjects			
Adults (18-64 years)	1	22	3
From 65-84 years	2	14	2
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	59.7	60.3	60.4
standard deviation	± 24.8	± 12.4	± 9.8
Sex: Female, Male Units: Participants			
Female	1	19	1
Male	2	17	4

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	36	5
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	2	1
Not Hispanic or Latino	1	11	1
Unknown or Not Reported	2	23	3

Reporting group values	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)	Total
Number of subjects	41	45	356
Age categorical			
Units: Subjects			
Adults (18-64 years)	12	38	221
From 65-84 years	29	7	135
Age Continuous			
Here "99999" = NA			
Units: years			
arithmetic mean	68.6	51.2	
standard deviation	± 8.0	± 12.8	-
Sex: Female, Male			
Units: Participants			
Female	0	45	170
Male	41	0	186
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	9
White	40	44	335
More than one race	0	0	0
Unknown or Not Reported	1	0	7
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	3	3	39
Not Hispanic or Latino	6	13	135
Unknown or Not Reported	32	29	182

End points

End points reporting groups

Reporting group title	Part 1A: BMS-986249 240 mg Monotherapy
Reporting group description: BMS-986249 240 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 800 mg Monotherapy
Reporting group description: BMS-986249 800 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 1600 mg Monotherapy
Reporting group description: BMS-986249 1600 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 2400 mg Monotherapy
Reporting group description: BMS-986249 2400 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1A: BMS-986249 1600 mg Q8W Monotherapy
Reporting group description: BMS-986249 1600 mg IV every 8 weeks (Q8W), up to 2 years	
Reporting group title	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination
Reporting group description: BMS-986249 240 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Reporting group title	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination
Reporting group description: BMS-986249 800 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Reporting group title	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Reporting group description: BMS-986249 1200 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years	
Reporting group title	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination
Reporting group description: BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination
Reporting group description: BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination
Reporting group description: BMS-986249 1600 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 2A Arm A: BMS-986249 240 mg Q3W + Nivo 360 mg Q3W
Reporting group description: BMS-986249 240 mg IV every 3 weeks (Q3W) + nivolumab 360 mg IV every 3 weeks (Q3W) (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) (maintenance), up to 2 years.	
Reporting group title	Part 2A Arm B: BMS-986249 800 mg + Nivo 480 mg Q4W
Reporting group description: BMS-986249 800 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Reporting group description: BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years	
Reporting group title	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W

Reporting group description:

Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

Reporting group title	Part 2A Arm E: Nivo 480 mg Q4W Monotherapy
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Reporting group description:

Nivolumab 480 mg IV every 4 weeks (Q4W) monotherapy, up to 2 years.

Reporting group title	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W
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Reporting group description:

BMS-986249 600 mg IV every 4 weeks (Q4W) + nivolumab 480 mg IV Q4W, up to 2 years.

Reporting group title	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
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Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years

Reporting group title	Part 2B: Cohort 2 (Metastatic CRPC)
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Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Reporting group title	Part 2B: Cohort 3 (Unresectable TNBC)
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Reporting group description:

BMS-986249 1200 mg IV every 8 weeks (Q8W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Subject analysis set title	Part 2A Arm C: BMS-986249 1200 mg Q6W + Nivo 480 mg Q4W
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Subject analysis set type	Per protocol
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Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W)

Subject analysis set title	Part 2A Arm D: Ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W
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Subject analysis set type	Per protocol
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Subject analysis set description:

Ipilimumab 3 mg/kg IV every 3 weeks (Q3W) + nivolumab 1 mg/kg IV Q3W (4 doses), then nivolumab 480 mg IV every 4 weeks (Q4W), monotherapy, up to 2 years.

Subject analysis set title	Part 2A Arm F: BMS-986249 1200 mg Q6W + Nivo 480 mg Q4W
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Subject analysis set type	Per protocol
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Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Subject analysis set title	Part 2B: Cohort 1 (Advanced or Intermediate HCC):
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Subject analysis set type	Per protocol
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Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Subject analysis set title	Part 2B Cohort 2 (Metastatic CRPC)
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Subject analysis set type	Per protocol
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Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years.

Subject analysis set title	Part 2B: Cohort 3 (Unresectable TNBC)
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Subject analysis set type	Per protocol
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Subject analysis set description:

BMS-986249 1200 mg IV every 6 weeks (Q6W) + nivolumab 480 mg IV every 4 weeks (Q4W), up to 2 years

Primary: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) - Part 1 A and 1 B

End point title	Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) - Part 1 A and 1 B ^{[1][2]}
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End point description:

Adverse Events (AEs):

Adverse events are any unwanted or harmful medical occurrences in a participant who receives a study drug or intervention. These events may or may not be related to the treatment.

Serious Adverse Events (SAEs):

Serious adverse events are adverse events that result in death, are life-threatening, require hospitalization or prolong existing hospitalization, cause significant disability or incapacity, or result in a birth defect.

End point type	Primary
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End point timeframe:

From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)

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 further statistical analysis done for this endpoint

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	10	1
Units: Participants				
Adverse events (AEs)	6	11	10	1
Serious adverse events (SAEs)	4	8	8	1
Adverse events (AEs) leading to discontinuation	0	2	4	0

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W + Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9
Units: Participants				
Adverse events (AEs)	11	12	11	9
Serious adverse events (SAEs)	7	8	7	7
Adverse events (AEs) leading to discontinuation	2	3	5	4

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1600 mg Q8W + Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	9	
Units: Participants				
Adverse events (AEs)	13	10	9	
Serious adverse events (SAEs)	10	8	7	
Adverse events (AEs) leading to discontinuation	2	5	3	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with Adverse Events (AEs) meeting Protocol-Defined Dose-Limiting Toxicity (DLT) Criteria - Part 1 A and 1 B

End point title	Number of participants with Adverse Events (AEs) meeting Protocol-Defined Dose-Limiting Toxicity (DLT) Criteria - Part 1 A and 1 B ^{[3][4]}
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End point description:

Dose-limiting toxicities (DLTs) were defined by the incidence, intensity, and duration of adverse events (AEs) possibly related to study treatment during the 5-week (35-day) DLT evaluation period for both BMS-986249 monotherapy and combination therapy. Participants who received at least 2 doses and completed or discontinued due to a DLT within this period were considered DLT-evaluable. Those who withdrew or received less than 2 doses for reasons other than a DLT were not DLT-evaluable and could be replaced. Any drug-related AE meeting DLT criteria resulted in discontinuation of study treatment. DLTs guided dose escalation and helped define the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D).

End point type	Primary
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End point timeframe:

From first dose until 5 weeks after first dose of study medicine (up to approximately 5 weeks)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	10	1
Units: Participants	0	0	1	0

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9

Units: Participants	1	0	1	0
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End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	9	
Units: Participants	0	3	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who Died – Part 1 A and 1 B

End point title	Number of Participants who Died – Part 1 A and 1 B ^[5] ^[6]
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End point description:

End point type	Primary
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End point timeframe:

From enrollment until the date of death from any cause (up to approximately 83 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	10	1
Units: Participants	4	10	7	1

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9
Units: Participants	6	11	8	7

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	9	
Units: Participants	8	9	4	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Shifts from Baseline in Laboratory Test results – Part 1 A and 1 B

End point title	Number of Participants with Shifts from Baseline in Laboratory Test results – Part 1 A and 1 B ^{[7][8]}
End point description:	Number of Participants with Shifts from Baseline in Laboratory Tests
End point type	Primary
End point timeframe:	From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	9	1
Units: Participants				
HEMOGLOBIN	3	4	7	1
PLATELET COUNT	1	1	2	0
LEUKOCYTES, LOCAL LAB	1	0	1	0
ABSOLUTE NEUTROPHIL COUNT DRV	0	0	0	0
LYMPHOCYTES (ABSOLUTE)	2	1	3	0
LYMPHOCYTES (ABSOLUTE), LOCAL LAB	2	7	6	0
CREATININE, LOCAL LAB	0	4	1	0
ALKALINE PHOSPHATASE (ALP) LOCAL LAB	1	7	1	1
ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB	2	4	2	0
ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB	2	7	3	1

BILIRUBIN, TOTAL, LOCAL LAB	2	1	1	1
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End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9
Units: Participants				
HEMOGLOBIN	4	10	9	6
PLATELET COUNT	0	0	3	0
LEUKOCYTES, LOCAL LAB	2	3	4	0
ABSOLUTE NEUTROPHIL COUNT DRV	2	0	4	0
LYMPHOCYTES (ABSOLUTE)	0	0	1	0
LYMPHOCYTES (ABSOLUTE), LOCAL LAB	3	6	5	5
CREATININE, LOCAL LAB	1	1	1	1
ALKALINE PHOSPHATASE (ALP) LOCAL LAB	3	5	4	6
ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB	2	4	4	4
ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB	3	4	6	4
BILIRUBIN, TOTAL, LOCAL LAB	1	1	5	2

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	9	
Units: Participants				
HEMOGLOBIN	7	7	4	
PLATELET COUNT	2	3	1	
LEUKOCYTES, LOCAL LAB	2	3	1	
ABSOLUTE NEUTROPHIL COUNT DRV	1	2	2	
LYMPHOCYTES (ABSOLUTE)	2	0	2	
LYMPHOCYTES (ABSOLUTE), LOCAL LAB	1	4	6	
CREATININE, LOCAL LAB	3	5	2	
ALKALINE PHOSPHATASE (ALP) LOCAL LAB	5	6	2	
ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB	5	4	3	
ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB	5	5	3	
BILIRUBIN, TOTAL, LOCAL LAB	4	2	3	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment-Related Grade 3-5 Adverse Events (AEs) Within 24 weeks – Part 2 A Arms C, D and F, and Part 2 B

End point title	Number of Participants with Treatment-Related Grade 3-5 Adverse Events (AEs) Within 24 weeks – Part 2 A Arms C, D and F, and Part 2 B ^{[9][10]}
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End point description:

Adverse Events (AEs):

Adverse events are any unwanted or harmful medical occurrences in a participant who receives a study drug or intervention. These events may or may not be related to the treatment.

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention needed.

Grade 2: Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate activities.

Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling.

Grade 4: Life-threatening consequences; urgent intervention required.

Grade 5: Death related to the adverse event.

End point type	Primary
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End point timeframe:

From first dose until 24 weeks after first dose (up to approximately 24 weeks)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	59	36	5
Units: Participants	24	18	14	4

End point values	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	45		
Units: Participants	13	11		

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR) as Assessed by Investigator - Part 2 A Arm C and F

End point title	Objective Response Rate (ORR) as Assessed by Investigator - Part 2 A Arm C and F ^{[11][12]}
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End point description:

Objective response rate (ORR) is defined as the percent of participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1:

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to <10mm.

Partial Response (PR): At least a30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Primary
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End point timeframe:

From randomization until progression or death from any cause (up to approximately 83 months)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No further statistical analysis done for this endpoint

[12] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	36		
Units: Percentage of participants				
number (confidence interval 95%)	36.2 (24.0 to 49.9)	52.8 (35.5 to 69.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Deterioration in Part 2A (Arm C, D and F)

End point title	Time to Deterioration in Part 2A (Arm C, D and F) ^[13]
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End point description:

TTD in Global Health Status/QoL and Physical Functioning will be defined as the time from randomization until a clinically meaningful decline (i.e., reduction ≥ 10 points) from baseline in EORTC QLQ-C30 global health/quality of life subscale score and Physical Functioning Scale score.

End point type	Secondary
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End point timeframe:

Approximately up to 6 months

Notes:

[13] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	59	36	
Units: Months				
median (confidence interval 95%)	3.52 (1.87 to 5.29)	4.37 (1.51 to 5.78)	2.79 (1.22 to 5.65)	

Statistical analyses

No statistical analyses for this end point

Secondary: Safety Related Events in Part 2A (Arm C, D and F) and 2B

End point title	Safety Related Events in Part 2A (Arm C, D and F) and 2B ^[14]
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End point description:

Adverse Events (AEs):

Adverse events are any unwanted or harmful medical occurrences in a participant who receives a study drug or intervention. These events may or may not be related to the treatment.

Serious Adverse Events (SAEs):

Serious adverse events are adverse events that result in death, are life-threatening, require hospitalization or prolong existing hospitalization, cause significant disability or incapacity, or result in a birth defect.

End point type	Secondary
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End point timeframe:

From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)

Notes:

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	58	36	5
Units: Template				
Adverse Events	57	57	35	5
Serious Adverse Events	41	28	20	5
AEs leading to discontinuation	24	25	20	4
Deaths	27	24	10	4

End point values	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	45		
Units: Template				
Adverse Events	40	45		
Serious Adverse Events	29	25		
AEs leading to discontinuation	13	13		
Deaths	26	28		

Statistical analyses

No statistical analyses for this end point

Secondary: BOR of PSA and PCWG3 Response Rate in Part 2B Cohort 2

End point title	BOR of PSA and PCWG3 Response Rate in Part 2B Cohort 2 ^[15]
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End point description:

Best Overall Response (BOR) is defined as the best response recorded from the start of randomization or first dosing date until the date of objectively documented PD based on RECIST v1.1 criteria or PCWG3 (for prostate cancer), or the date of subsequent therapy (including tumor directed radiotherapy and tumor-directed surgery which are not for palliative purpose), whichever occurs first.

End point type	Secondary
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End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 2B: Cohort 2 (Metastatic CRPC)			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of participants				
number (confidence interval 95%)				
PSA Response Rate	14.6 (5.6 to 29.2)			
PCWG3 Response Rate	9.8 (2.7 to 23.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival

End point title	Progression Free Survival ^[16]
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End point description:

Defined as the time between the date of randomization (Part 2A), or first dosing for Part 1 and supplemental analysis in Part 2A, and the date of first documented tumor progression, based on

investigator assessments (per RECIST v1.1 criteria or PCWG3), or death due to any cause, whichever occurs first.

Here "-99999 and 99999" = NA

End point type	Secondary
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End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	10	1
Units: Months				
median (confidence interval 95%)	1.74 (1.41 to 99999)	1.77 (1.15 to 1.84)	1.69 (0.53 to 3.25)	3.55 (-99999 to 99999)

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9
Units: Months				
median (confidence interval 95%)	1.68 (1.05 to 99999)	2.33 (1.68 to 3.32)	1.71 (0.85 to 14.23)	3.32 (1.22 to 4.40)

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	10	58
Units: Months				
median (confidence interval 95%)	1.92 (0.59 to 7.13)	1.91 (1.02 to 99999)	4.35 (0.92 to 12.45)	6.51 (4.90 to 12.52)

End point values	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	36	5	41
Units: Months				
median (confidence interval 95%)	4.73 (2.89 to 9.76)	10.38 (6.74 to 99999)	2.99 (1.77 to 99999)	5.62 (3.68 to 8.28)

End point values	Part 2B: Cohort 3 (Unresectable TNBC)			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Months				
median (confidence interval 95%)	3.35 (1.84 to 5.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response ^[17]
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End point description:

Defined as the time between the date of first documented response (CR or PR) to the date of the first documented tumor progression, as determined by RECIST v1.1 or PCWG3 criteria, or death due to any cause, whichever occurs first. Subjects who start subsequent therapy without a prior reported progression will be censored at the last evaluable tumor assessments prior to initiation of the subsequent anticancer therapy. Subjects who die without a reported prior progression will be considered to have progressed on the date of their death. Subjects who neither progress nor die, DOR will be censored on the date of their last evaluable tumor assessment. DOR will be evaluated for responders (confirmed CR or PR) only.

Here "99999" = NA

End point type	Secondary
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End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[18]	0 ^[19]	0 ^[20]	0 ^[21]
Units: Months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

- [18] - No subjects with events
- [19] - No subjects with events
- [20] - No subjects with events
- [21] - No subjects with events

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[22]	0 ^[23]	2	0 ^[24]
Units: Months				
median (full range (min-max))	(to)	(to)	99999 (12.48 to 99999)	(to)

Notes:

- [22] - No subjects with events
- [23] - No subjects with events
- [24] - No subjects with events

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	21
Units: Months				
median (full range (min-max))	15.80 (1.68 to 99999)	99999 (1.74 to 99999)	99999 (8.97 to 99999)	26.84 (7.85 to 99999)

End point values	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	19	0 ^[25]	4
Units: Months				
median (full range (min-max))	99999 (7.2 to 99999)	99999 (6.47 to 99999)	(to)	99999 (99999 to 99999)

Notes:

- [25] - No subjects with events

End point values	Part 2B: Cohort 3 (Unresectable TNBC)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: Months				
median (full range (min-max))	21.49 (3.68 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response

End point title	Time to Response ^[26]
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End point description:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

End point type	Secondary
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End point timeframe:

From first dose to first objective response (Approximately up to 3 Months)

Notes:

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

Justification: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[27]	0 ^[28]	0 ^[29]	0 ^[30]
Units: Months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[27] - No Subjects with Events

[28] - No Subjects with Events

[29] - No Subjects with Events

[30] - No Subjects with Events

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[31]	0 ^[32]	2	0 ^[33]
Units: Months				
median (full range (min-max))	(to)	(to)	2.76 (1.8 to 3.7)	(to)

Notes:

[31] - No Subjects with Events

[32] - No Subjects with Events

[33] - No Subjects with Events

End point values	Part 1B: BMS-986249 800	Part 1B: BMS-986249 1200	Part 1B: BMS-986249 1600	Part 2A Arm C: BMS-986249
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	mg Q8W + Nivolumab Combination	mg Q8W+ Nivo Combination	mg Q8W+ Nivolumab Combination	1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	21
Units: Months				
median (full range (min-max))	1.74 (1.7 to 3.9)	3.48 (3.48 to 5.4)	4.01 (3.5 to 4.3)	2.86 (2.1 to 8.6)

End point values	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	19	0 ^[34]	4
Units: Months				
median (full range (min-max))	2.83 (2.0 to 26.4)	2.83 (2.66 to 4.44)	(to)	2.84 (1.7 to 3.9)

Notes:

[34] - No Subjects with Events

End point values	Part 2B: Cohort 3 (Unresectable TNBC)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: Months				
median (full range (min-max))	1.87 (1.74 to 2.76)			

Statistical analyses

No statistical analyses for this end point

Secondary: ORR by Investigator

End point title	ORR by Investigator ^[35]
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End point description:

Objective response rate (ORR) is defined as the percent of participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 or Prostate Cancer Working Group (PCWG) 3. For both RECIST v1.1 and PCWG3:

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to <10mm.

Partial Response (PR): At least a30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Secondary
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End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[35] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	10	1
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 45.9)	0 (0.0 to 28.5)	0 (0.0 to 30.8)	0 (0.0 to 97.5)

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 28.5)	0 (0.0 to 26.5)	18.2 (2.3 to 51.8)	0 (0.0 to 33.6)

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	10	58
Units: Percentage of participants				
number (confidence interval 95%)	23.1 (5.0 to 53.8)	33.3 (7.5 to 70.1)	30.0 (6.7 to 65.2)	36.2 (24.0 to 49.9)

End point values	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	36	5	41
Units: Percentage of participants				
number (confidence interval 95%)	35.6 (23.6 to 49.1)	52.8 (35.5 to 69.6)	0 (0.0 to 52.2)	9.8 (2.7 to 23.1)

End point values	Part 2B: Cohort 3 (Unresectable TNBC)			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Percentage of participants				
number (confidence interval 95%)	15.6 (6.5 to 29.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) as Assessed by Investigator - Part 1 A, 1B, 2A (Arms C,D,F) and 2B

End point title	Objective Response Rate (ORR) as Assessed by Investigator - Part 1 A, 1B, 2A (Arms C,D,F) and 2B ^[36]
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End point description:

Objective response rate (ORR) is defined as the percent of participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 or Prostate Cancer Working Group (PCWG) 3. For both RECIST v1.1 and PCWG3:

Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to <10mm.

Partial Response (PR): At least a30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Secondary
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End point timeframe:

From first dose (Parts 1 A and B) or randomization (Part 2 B) progression or death from any cause (up to approximately 83 months)

Notes:

[36] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	11	10	1
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 45.9)	0 (0.0 to 28.5)	0 (0.0 to 30.8)	0 (0.0 to 97.5)

End point values	Part 1A: BMS-986249 1600 mg Q8W	Part 1B: BMS-986249 240 mg Q4W +	Part 1B: BMS-986249 800 mg Q4W+ Nivo	Part 1B: BMS-986249 1200 mg Q4W +
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	Monotherapy	Nivo Combination	Combination	Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	9
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 28.5)	0 (0.0 to 26.5)	18.2 (2.3 to 51.8)	0 (0.0 to 33.6)

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	10	3
Units: Percentage of participants				
number (confidence interval 95%)	23.1 (5.0 to 53.8)	33.3 (7.5 to 70.1)	30.0 (6.7 to 65.2)	31.0 (19.5 to 44.5)

End point values	Part 2A Arm D: ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	36		
Units: Percentage of participants				
number (confidence interval 95%)	27.1 (16.4 to 40.3)	50.0 (32.9 to 67.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax and Ctau of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B

End point title	Cmax and Ctau of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B ^[37]
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End point description:

Cmax: The highest concentration of BMS-986249 in the blood after dosing.

Ctau: The concentration of BMS-986249 in the blood at the end of a dosing interval, just before the next dose

Here "99999" = NA

End point type	Secondary
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End point timeframe:

On Cycle 1 Day 1, Cycle 3 Day 1, Cycle 4 Day 1, Cycle 5 Day 1 (each cycle=28 days)

Notes:

[37] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	11	10	1
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cmax Cycle 1 Day 1	398 (± 24)	1451 (± 39)	3569 (± 27)	4965 (± 99999)
Cmax C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cmax Cycle 4 Day 1	432 (± 55)	1425 (± 14)	5299 (± 99999)	3910 (± 99999)
Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Ctau Cycle 1 Day 1	7.69 (± 4151)	174 (± 71)	344 (± 418)	385 (± 99999)
Ctau C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Ctau Cycle 4 Day 1	51.6 (± 255)	1425 (± 14)	99999 (± 99999)	236 (± 99999)
CTau C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	8
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cmax Cycle 1 Day 1	2735 (± 31)	454 (± 27)	1322 (± 40)	1729 (± 39)
Cmax C3D1	2919 (± 48)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cmax Cycle 4 Day 1	99999 (± 99999)	570 (± 9)	1706 (± 21)	1436 (± 99999)
Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Ctau Cycle 1 Day 1	52.6 (± 181)	45.8 (± 322)	143 (± 51)	159 (± 58)
Ctau C3D1	149 (± 24)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Ctau Cycle 4 Day 1	99999 (± 99999)	170 (± 11)	115 (± 310)	107 (± 99999)
CTau C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	10	56
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cmax Cycle 1 Day 1	1397 (± 27)	2105 (± 26)	3146 (± 38)	2274 (± 49)
Cmax C3D1	1894 (± 33)	1817 (± 32)	2771 (± 28)	99999 (± 99999)
Cmax Cycle 4 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	2022 (± 50)
Ctau Cycle 1 Day 1	20.2 (± 206)	99999 (± 99999)	58.7 (± 190)	57.9 (± 300)
Ctau C3D1	94.4 (± 7)	99999 (± 99999)	152 (± 45)	99999 (± 99999)
Ctau Cycle 4 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CTau C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	100 (± 83)

End point values	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	5	39	38
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cmax Cycle 1 Day 1	1114 (± 34)	1752 (± 40)	2050 (± 27)	2404 (± 41)
Cmax C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cmax Cycle 4 Day 1	930 (± 38)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Ctau Cycle 1 Day 1	153 (± 34)	82.3 (± 61)	79.3 (± 98)	66.2 (± 153)
Ctau C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Ctau Cycle 4 Day 1	151 (± 53)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
CTau C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-T) and AUC(TAU) of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B

End point title	AUC(0-T) and AUC(TAU) of BMS-986249 - Part 1 A and B, Part 2 A Arms C and F, Part 2 B ^[38]
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End point description:

AUC(0-T): The total amount of BMS-986249 in the blood from the time it is given until a specific time point.

AUC(TAU): The total amount of BMS-986249 in the blood over one dosing interval

Here "99999" = NA

End point type	Secondary
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End point timeframe:

On Cycle 1 Day 1, Cycle 3 Day 1, Cycle 4 Day 1, Cycle 5 Day 1 (each cycle=28 days)

Notes:

[38] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	11	10	1
Units: ng*h/mL				
geometric mean (geometric coefficient of variation)				
AUC (0-T) Cycle 1 Day 1	77826 (± 48)	294432 (± 39)	745654 (± 40)	991294 (± 99999)
AUC (Tau) Cycle 1 Day 1	67094 (± 53)	288621 (± 37)	629431 (± 55)	999415 (± 99999)
AUC (0-T) Cycle 4 Day 1	432 (± 55)	284353 (± 45)	99999 (± 99999)	687899 (± 99999)
AUC (Tau) Cycle 4 Day 1	51.6 (± 255)	147763 (± 25)	114154 (± 99999)	536764 (± 99999)
AUC (0-T) C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (0-T) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	8
Units: ng*h/mL				
geometric mean (geometric coefficient of variation)				
AUC (0-T) Cycle 1 Day 1	671019 (± 48)	96709 (± 49)	292555 (± 32)	378115 (± 31)
AUC (Tau) Cycle 1 Day 1	484593 (± 74)	88780 (± 61)	282516 (± 32)	326037 (± 40)
AUC (0-T) Cycle 4 Day 1	99999 (± 99999)	181278 (± 9)	338096 (± 49)	255093 (± 99999)
AUC (Tau) Cycle 4 Day 1	99999 (± 99999)	139951 (± 71)	223315 (± 64)	255093 (± 99999)
AUC (0-T) C3D1	1121470 (± 53)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) C3D1	1121470 (± 53)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (0-T) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	10	56
Units: ng*h/mL				
geometric mean (geometric coefficient of variation)				
AUC (0-T) Cycle 1 Day 1	325275 (± 35)	521156 (± 36)	688556 (± 29)	612513 (± 44)
AUC (Tau) Cycle 1 Day 1	259533 (± 35)	458972 (± 41)	532540 (± 43)	464205 (± 81)
AUC (0-T) Cycle 4 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) Cycle 4 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (0-T) C3D1	611831 (± 19)	780896 (± 45)	972214 (± 28)	99999 (± 99999)
AUC (Tau) C3D1	611831 (± 19)	780896 (± 45)	937806 (± 25)	99999 (± 99999)
AUC (0-T) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	675816 (± 33)
AUC (Tau) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	564180 (± 52)

End point values	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)
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	Q4W			
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	5	39	38
Units: ng*h/mL				
geometric mean (geometric coefficient of variation)				
AUC (0-T) Cycle 1 Day 1	255384 (± 23)	653770 (± 7)	638435 (± 24)	696815 (± 34)
AUC (Tau) Cycle 1 Day 1	231346 (± 48)	407104 (± 56)	438370 (± 70)	554691 (± 52)
AUC (0-T) Cycle 4 Day 1	260319 (± 35)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) Cycle 4 Day 1	229430 (± 37)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (0-T) C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (0-T) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AUC (Tau) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation Index for Cmax (AI_Cmax) and Accumulation Index for AUC (AI_AUC) of BMS-986249 - Part 1 A and B, Part 2 A Arms C, D and F, Part 2 B

End point title	Accumulation Index for Cmax (AI_Cmax) and Accumulation Index for AUC (AI_AUC) of BMS-986249 - Part 1 A and B, Part 2 A Arms C, D and F, Part 2 B ^[39]
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End point description:

AI_Cmax: How much the highest concentration of BMS-986249 increases after multiple doses compared to a single dose.

AI_AUC: How much the total exposure to BMS-986249 increases after multiple doses compared to a single dose.

Here "99999" = NA

End point type	Secondary
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End point timeframe:

On Cycle 1 Day 1, Cycle 3 Day 1, Cycle 4 Day 1, Cycle 5 Day 1 (each cycle=28 days)

Notes:

[39] - 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: as per protocol, these are the defined arms for this endpoint

End point values	Part 1A: BMS-986249 240 mg Monotherapy	Part 1A: BMS-986249 800 mg Monotherapy	Part 1A: BMS-986249 1600 mg Monotherapy	Part 1A: BMS-986249 2400 mg Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	11	10	1
Units: ratio				
geometric mean (geometric coefficient of variation)				

AI (AUC) Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) Cycle 4 Day 1	1.29 (± 11)	1.07 (± 29)	99999 (± 99999)	0.694 (± 99999)
AI Cmax Cycle 4 Day 1	1.02 (± 14)	324 (± 99999)	1.32 (± 99999)	0.788 (± 99999)
AI (AUC) C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1A: BMS-986249 1600 mg Q8W Monotherapy	Part 1B: BMS-986249 240 mg Q4W + Nivo Combination	Part 1B: BMS-986249 800 mg Q4W+ Nivo Combination	Part 1B: BMS-986249 1200 mg Q4W + Nivolumab Combination
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	11	8
Units: ratio				
geometric mean (geometric coefficient of variation)				
AI (AUC) Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) Cycle 4 Day 1	99999 (± 99999)	1.54 (± 1)	1.23 (± 16)	1.29 (± 99999)
AI Cmax Cycle 4 Day 1	99999 (± 99999)	1.28 (± 10)	1.25 (± 17)	1.62 (± 99999)
AI (AUC) C3D1	1.35 (± 7)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax C3D1	1.17 (± 3)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1B: BMS-986249 800 mg Q8W + Nivolumab Combination	Part 1B: BMS-986249 1200 mg Q8W+ Nivo Combination	Part 1B: BMS-986249 1600 mg Q8W+ Nivolumab Combination	Part 2A Arm C: BMS-986249 1200 mg Q8W + Nivo 480 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	9	10	56
Units: ratio				
geometric mean (geometric coefficient of variation)				

AI (AUC) Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) Cycle 4 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax Cycle 4 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) C3D1	1.82 (± 43)	1.3 (± 17)	1.46 (± 11)	99999 (± 99999)
AI Cmax C3D1	1.58 (± 85)	0.918 (± 16)	0.978 (± 14)	99999 (± 99999)
AI (AUC) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.13 (± 18)
AI Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	1.11 (± 53)

End point values	Part 2A Arm F: BMS-986249 600 mg Q4W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC)	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	5	39	38
Units: ratio				
geometric mean (geometric coefficient of variation)				
AI (AUC) Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax Cycle 1 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) Cycle 4 Day 1	0.971 (± 24)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax Cycle 4 Day 1	0.899 (± 64)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI (AUC) C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
AI Cmax C5D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Shifts from Baseline in Laboratory Test results – Part 2A (Arms C and F) and 2B

End point title	Number of Participants with Shifts from Baseline in Laboratory Test results – Part 2A (Arms C and F) and 2B
End point description:	

End point type	Secondary
End point timeframe:	
From first dose until 100 days after last dose of study therapy (up to approximately 38 weeks)	

End point values	Part 2A Arm C: BMS-986249 1200 mg Q6W + Nivo 480 mg Q4W	Part 2A Arm D: Ipilimumab 3 mg/kg Q3W + Nivo 1 mg/kg Q3W	Part 2A Arm F: BMS-986249 1200 mg Q6W + Nivo 480 mg Q4W	Part 2B: Cohort 1 (Advanced or Intermediate HCC):
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	57	58	36	5
Units: Participants				
HEMOGLOBIN	42	43	25	3
PLATELET COUNT	13	10	7	2
LEUKOCYTES, LOCAL LAB	12	10	6	0
ABSOLUTE NEUTROPHIL COUNT DRV	7	8	6	0
LYMPHOCYTES (ABSOLUTE)	9	19	10	0
LYMPHOCYTES (ABSOLUTE), LOCAL LAB	23	12	10	2
CREATININE, LOCAL LAB	20	17	10	3
ALKALINE PHOSPHATASE (ALP) LOCAL LAB	24	30	19	3
ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB	38	40	23	4
ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB	27	40	22	3
BILIRUBIN, TOTAL, LOCAL LAB	12	18	7	3

End point values	Part 2B Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	45		
Units: Participants				
HEMOGLOBIN	32	33		
PLATELET COUNT	15	12		
LEUKOCYTES, LOCAL LAB	9	14		
ABSOLUTE NEUTROPHIL COUNT DRV	9	10		
LYMPHOCYTES (ABSOLUTE)	11	11		
LYMPHOCYTES (ABSOLUTE), LOCAL LAB	9	17		
CREATININE, LOCAL LAB	14	5		
ALKALINE PHOSPHATASE (ALP) LOCAL LAB	17	25		
ALANINE AMINOTRANSFERASE (ALT), LOCAL LAB	18	27		
ASPARTATE AMINOTRANSFERASE (AST), LOCAL LAB	19	31		
BILIRUBIN, TOTAL, LOCAL LAB	12	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events and Serious Adverse Events: (From first dose to last dose + 100 days): Approximately 38 weeks

All-Cause mortality (From randomization to end of study): Approximately 83 Months

Adverse event reporting additional description:

The number at Risk for All-Cause Mortality represents all Randomized Participants. The number at Risk for Serious Adverse Events and Other (Not Including Serious) Adverse Events represents all participants that received at least 1 dose of study medication

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Part 1A: BMS-986249 Monotherapy 2400 Q4W
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Reporting group description:

BMS-986249 2400 mg IV Q4W, up to 2 years

Reporting group title	Part 1A: BMS-986249 Monotherapy 1600 Q4W
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Reporting group description:

BMS-986249 1600 mg IV Q4W, up to 2 years

Reporting group title	Part 1A: BMS-986249 Monotherapy BMS 800 Q4W
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Reporting group description:

BMS-986249 800 mg IV Q4W, up to 2 years

Reporting group title	Part 1A: BMS-986249 Monotherapy 240 mg IV Q4W
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Reporting group description:

BMS-986249 240 mg IV Q4W, up to 2 years

Reporting group title	Part 1A: BMS-986249 Monotherapy 1600 Q8W
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Reporting group description:

BMS-986249 1600 mg IV Q8W, up to 2 years

Reporting group title	Part 1B: BMS-986249 800mg Q8W+ Nivolumab Combination
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Reporting group description:

BMS-986249 800 mg IV Q8W + Nivolumab 480 mg IV Q8W

Reporting group title	Part 1B: BMS-986249 1200mg Q4W + Nivolumab Combination
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Reporting group description:

BMS-986249 1200 mg IV Q4W + Nivolumab 480 mg IV Q6W

Reporting group title	Part 1B: BMS-986249 800mg Q4W + Nivolumab Combination
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Reporting group description:

BMS-986249 800 mg IV Q4W + Nivolumab 480 mg IV Q4W

Reporting group title	Part 1B: BMS-986249 240mg Q4W + Nivolumab Combination
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Reporting group description:

BMS-986249 240 mg IV Q4W + Nivolumab 480 mg IV Q4W

Reporting group title	Part 1B: BMS-986249 1200mg Q8W+ Nivolumab Combination
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Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

Reporting group title	Part 1B: BMS-986249 1600mg Q8W+ Nivolumab Combination
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Reporting group description:

BMS-986249 1600 mg IV Q8W + Nivolumab 480 mg IV Q4W

Reporting group title	Part 2A: Melanoma Arms BMS-986249 240mg IV Q3W
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Reporting group description:

BMS-986249 240 mg IV Q3W + Nivolumab 360 mg IV Q3W (14 doses), then Nivolumab 480 mg IV Q4W (maintenance)

Reporting group title	Part 2A: Melanoma Arms BMS-986249 800mg IV Q3W
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Reporting group description:

BMS-986249 800 mg IV Q3W + Nivolumab 480 mg IV Q3W (14 doses), then Nivolumab 480 mg IV Q4W (maintenance)

Reporting group title	Part 2A: Melanoma Arms BMS-986249 1200mg IV Q3W
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Reporting group description:

BMS-986249 1200 mg IV Q3W + Nivolumab 480 mg IV Q3W (14 doses), then Nivolumab 480 mg IV Q4W (maintenance)

Reporting group title	Part 2A: Melanoma Arms Ipilimumab 3mg/kg IV Q3W
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Reporting group description:

Ipilimumab 3 mg/kg IV Q3W + Nivolumab 1 mg/kg IV Q3W (4 doses), then Nivolumab 480 mg IV Q4W (maintenance), up to 2 years

Reporting group title	Part 2A: Melanoma Arms Nivolumab Mono
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Reporting group description:

Nivolumab 480 mg IV Q4W Monotherapy

Reporting group title	Part 2A: Melanoma Arms BMS-986249 600mg IV Q8W
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Reporting group description:

BMS-986249 600 mg IV Q8W + Nivolumab 480 mg IV Q8W (Melanoma-specific combination)

Reporting group title	Part 2B: Cohort 1 (HCC)
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Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

Reporting group title	Part 2B: Cohort 2 (Metastatic CRPC)
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Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

Reporting group title	Part 2B: Cohort 3 (Unresectable TNBC)
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Reporting group description:

BMS-986249 1200 mg IV Q8W + Nivolumab 480 mg IV Q8W

Serious adverse events	Part 1A: BMS-986249 Monotherapy 2400 Q4W	Part 1A: BMS-986249 Monotherapy 1600 Q4W	Part 1A: BMS-986249 Monotherapy BMS 800 Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	8 / 10 (80.00%)	8 / 11 (72.73%)
number of deaths (all causes)	1	7	10
number of deaths resulting from adverse events	1	2	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	6 / 11 (54.55%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 6
Metastases to bone			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Arterial haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
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 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (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	0 / 1 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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-mediated myocarditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Uveitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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%)	2 / 10 (20.00%)	0 / 11 (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
Duodenal ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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-mediated enterocolitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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-mediated hepatic disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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-mediated hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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-mediated nephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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-mediated hypophysitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematoma muscle			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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%)	1 / 10 (10.00%)	0 / 11 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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	Part 1A: BMS-986249 Monotherapy 240 mg IV Q4W	Part 1A: BMS-986249 Monotherapy 1600 Q8W	Part 1B: BMS-986249 800mg Q8W+ Nivolumab Combination
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	7 / 11 (63.64%)	10 / 13 (76.92%)
number of deaths (all causes)	4	6	8
number of deaths resulting from adverse events	2	2	5

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	3 / 6 (50.00%)	1 / 11 (9.09%)	3 / 13 (23.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Metastases to bone			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Arterial haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
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 peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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-mediated myocarditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Uveitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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-mediated enterocolitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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-mediated hepatic disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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-mediated hepatitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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-mediated nephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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-mediated hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma muscle			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
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	Part 1B: BMS-986249 1200mg Q4W + Nivolumab Combination	Part 1B: BMS-986249 800mg Q4W + Nivolumab Combination	Part 1B: BMS-986249 240mg Q4W + Nivolumab Combination
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 9 (77.78%)	7 / 11 (63.64%)	8 / 12 (66.67%)
number of deaths (all causes)	7	8	11
number of deaths resulting from adverse events	5	3	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	5 / 9 (55.56%)	4 / 11 (36.36%)	3 / 12 (25.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 3	0 / 3
Metastases to bone			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Arterial haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (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
Peripheral embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Fatigue			
subjects affected / exposed	2 / 9 (22.22%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Fall			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Humerus fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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-mediated myocarditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (11.11%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (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
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Uveitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 9 (22.22%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	3 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ulcerative			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
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-mediated enterocolitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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-mediated hepatic disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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-mediated hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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-mediated nephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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-mediated hypophysitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma muscle			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 stenosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 sepsis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
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	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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	Part 1B: BMS-986249 1200mg Q8W+ Nivolumab Combination	Part 1B: BMS-986249 1600mg Q8W+ Nivolumab Combination	Part 2A: Melanoma Arms BMS-986249 240mg IV Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 9 (77.78%)	8 / 10 (80.00%)	3 / 3 (100.00%)
number of deaths (all causes)	4	9	0
number of deaths resulting from adverse events	3	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	2 / 9 (22.22%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	1 / 10 (10.00%)	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
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	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
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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-mediated myocarditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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			
Brain oedema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (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
Haemolysis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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			
Uveitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Autoimmune colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 9 (22.22%)	2 / 10 (20.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	3 / 4	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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-mediated enterocolitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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-mediated hepatic disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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-mediated hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	2 / 10 (20.00%)	0 / 3 (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
Immune-mediated nephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	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
Hyperthyroidism			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (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
Immune-mediated hypophysitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma muscle			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
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	Part 2A: Melanoma Arms BMS-986249 800mg IV Q3W	Part 2A: Melanoma Arms BMS-986249 1200mg IV Q3W	Part 2A: Melanoma Arms Ipilimumab 3mg/kg IV Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	42 / 57 (73.68%)	28 / 58 (48.28%)
number of deaths (all causes)	2	29	24
number of deaths resulting from adverse events	1	15	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	6 / 57 (10.53%)	6 / 58 (10.34%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 6	0 / 6
Metastases to bone			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Neoplasm malignant			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 2
Neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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			
Arterial haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
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%)	5 / 57 (8.77%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	6 / 9	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
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%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 3 (33.33%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune-mediated myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia pure red cell			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
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			
Uveitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	3 / 58 (5.17%)
occurrences causally related to treatment / all	0 / 0	2 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (1.75%)	0 / 58 (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%)	1 / 57 (1.75%)	0 / 58 (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
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (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
Hepatotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Immune-mediated hepatic disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Immune-mediated hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	1 / 58 (1.72%)
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-mediated nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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-mediated hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haematoma muscle			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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	1 / 3 (33.33%)	1 / 57 (1.75%)	0 / 58 (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
Clostridium difficile colitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (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
Pneumonia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
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%)	2 / 57 (3.51%)	0 / 58 (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
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
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	Part 2A: Melanoma Arms Nivolumab Mono	Part 2A: Melanoma Arms BMS-986249 600mg IV Q8W	Part 2B: Cohort 1 (HCC)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	20 / 36 (55.56%)	5 / 5 (100.00%)
number of deaths (all causes)	1	11	4
number of deaths resulting from adverse events	1	3	2

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 3 (33.33%)	3 / 36 (8.33%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Metastases to spine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Metastatic malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Neoplasm malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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

Vascular disorders			
Arterial haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Bleeding varicose vein			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Vasculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Peripheral embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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	0 / 3 (0.00%)	0 / 36 (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
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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 distress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	1 / 36 (2.78%)	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
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	1 / 36 (2.78%)	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

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Immune-mediated myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Myocarditis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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	0 / 3 (0.00%)	0 / 36 (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			
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Cerebral infarction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Facial paresis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Paraparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Transient ischaemic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Tremor			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	1 / 36 (2.78%)	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
Aplasia pure red cell			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Haemolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
Uveitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Autoimmune colitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	4 / 36 (11.11%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Intestinal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Nausea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Small intestinal perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hepatotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hypertransaminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Immune-mediated hepatic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Immune-mediated hepatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Jaundice cholestatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Immune-mediated nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 failure			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Hypopituitarism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Immune-mediated hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Thyroiditis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Haematoma muscle			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Encephalitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Klebsiella urinary tract infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Listeriosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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 influenzal			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Post procedural infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	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
Postoperative wound infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Pyelonephritis acute			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	1 / 36 (2.78%)	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
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Viral infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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			
Diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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 / 3 (0.00%)	0 / 36 (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
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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
Malnutrition			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (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

Serious adverse events	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)	
Total subjects affected by serious adverse events			
subjects affected / exposed	29 / 41 (70.73%)	25 / 45 (55.56%)	
number of deaths (all causes)	26	28	
number of deaths resulting from adverse events	13	10	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	4 / 41 (9.76%)	2 / 45 (4.44%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 4	0 / 2	
Metastases to bone			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	4 / 41 (9.76%)	5 / 45 (11.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 5	
Neoplasm progression			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Tumour haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Arterial haemorrhage			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bleeding varicose vein			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Performance status decreased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 41 (0.00%)	3 / 45 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood bilirubin increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Subdural haematoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated myocarditis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral ischaemia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paresis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplasia pure red cell			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolysis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heparin-induced thrombocytopenia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			

subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Uveitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune colitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diarrhoea			
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated enterocolitis			
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odynophagia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatotoxicity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatic disorder			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated nephritis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nephrolithiasis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopituitarism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hypophysitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			

Bacteraemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Device related infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis infectious			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella urinary tract infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Listeriosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 41 (4.88%)	3 / 45 (6.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyelonephritis			

subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	3 / 41 (7.32%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1A: BMS-986249 Monotherapy 2400 Q4W	Part 1A: BMS-986249 Monotherapy 1600 Q4W	Part 1A: BMS-986249 Monotherapy BMS 800 Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	9 / 10 (90.00%)	11 / 11 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Haematoma			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Application site reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	7 / 10 (70.00%)	4 / 11 (36.36%)
occurrences (all)	0	7	5
Hernia pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injection site extravasation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Swelling face			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Xerosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Breast pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	2
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pneumonitis			

subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Affective disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Disorientation			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Libido decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Blood albumin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
Blood calcium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	3	1
Blood glucose decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Blood prolactin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Cardiac murmur			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	1	1	4
Liver function test increased			

subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urine phosphorus increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urine calcium increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Femur fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Muscle strain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular access site erythema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Wound secretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2

Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Parkinson's disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 10 (30.00%)	3 / 11 (27.27%)
occurrences (all)	0	4	3
Eosinophilia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eyelid irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	1	1	2
Abdominal pain lower			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	7 / 10 (70.00%)	3 / 11 (27.27%)
occurrences (all)	0	9	5
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal motility disorder			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	5 / 10 (50.00%)	3 / 11 (27.27%)
occurrences (all)	0	6	3
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 10 (0.00%) 0	4 / 11 (36.36%) 5
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Autoimmune hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Jaundice cholestatic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Portal hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Acquired porokeratosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Keloid scar			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukoplakia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 1 (100.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
Palmar-plantar erythrodysesthesia			

syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Hypophysitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Thyroiditis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Inappropriate antidiuretic hormone secretion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Sacral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye infection bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatitis viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Soft tissue infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Staphylococcal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular access site infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 1 (0.00%)	4 / 10 (40.00%)	3 / 11 (27.27%)
occurrences (all)	0	4	3
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Electrolyte imbalance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	3	0
Hypermagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hyperlipasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	3	1
Hypochloraemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 10 (30.00%)	1 / 11 (9.09%)
occurrences (all)	0	5	1
Hypomagnesaemia			
subjects affected / exposed	1 / 1 (100.00%)	2 / 10 (20.00%)	2 / 11 (18.18%)
occurrences (all)	1	2	2
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	2 / 11 (18.18%)
occurrences (all)	0	2	2
Hypovolaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	3	1
Iron deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1A: BMS-986249 Monotherapy 240 mg IV Q4W	Part 1A: BMS-986249 Monotherapy 1600 Q8W	Part 1B: BMS-986249 800mg Q8W+ Nivolumab Combination
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	9 / 11 (81.82%)	12 / 13 (92.31%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cancer pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pallor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	3
Application site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Complication associated with device			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	2 / 11 (18.18%)	7 / 13 (53.85%)
occurrences (all)	1	2	8
Hernia pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site extravasation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	3 / 13 (23.08%)
occurrences (all)	0	2	3
Pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Performance status decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	4 / 13 (30.77%)
occurrences (all)	1	0	4
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Temperature intolerance subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	1 / 13 (7.69%) 1
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all) Breast pain subjects affected / exposed occurrences (all) Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Apnoea subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Dysphonia subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Hypoxia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 1 / 6 (16.67%) 1 0 / 6 (0.00%) 0 1 / 6 (16.67%) 1 1 / 6 (16.67%) 1 0 / 6 (0.00%) 0	0 / 11 (0.00%) 0 1 / 11 (9.09%) 1 0 / 11 (0.00%) 0 1 / 11 (9.09%) 2 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 1 / 13 (7.69%) 1 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 2 / 13 (15.38%) 2

Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Affective disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Libido decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	3 / 13 (23.08%)
occurrences (all)	1	0	3
Amylase increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Blood glucose decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood glucose increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood prolactin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Blood uric acid increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Liver function test increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urine phosphorus increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urine calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	2 / 13 (15.38%)
occurrences (all)	0	1	2

White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Injury, poisoning and procedural complications			
Fall subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	1 / 13 (7.69%) 1
Femur fracture subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	1 / 11 (9.09%) 1	2 / 13 (15.38%) 2
Muscle strain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Lip injury subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Rib fracture subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Vascular access site erythema			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Wound secretion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	3 / 13 (23.08%)
occurrences (all)	0	1	3
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Parkinson's disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	5 / 13 (38.46%)
occurrences (all)	1	1	5
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Neutropenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Hypoacusis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Eye disorders Dry eye subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Iridocyclitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Eyelid irritation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Swelling of eyelid subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 11 (0.00%) 0	0 / 13 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 11 (9.09%) 1	0 / 13 (0.00%) 0
Abdominal pain			

subjects affected / exposed	3 / 6 (50.00%)	2 / 11 (18.18%)	3 / 13 (23.08%)
occurrences (all)	3	2	3
Abdominal pain lower			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	3 / 6 (50.00%)	5 / 11 (45.45%)	6 / 13 (46.15%)
occurrences (all)	4	6	7
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	2 / 13 (15.38%)
occurrences (all)	0	1	3
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 6 (16.67%)	2 / 11 (18.18%)	4 / 13 (30.77%)
occurrences (all)	1	2	4
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	2 / 11 (18.18%)	3 / 13 (23.08%)
occurrences (all)	1	3	5
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Autoimmune hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypertransaminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Immune-mediated hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Jaundice cholestatic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Portal hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Acquired porokeratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	2
Keloid scar			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Leukoplakia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 13 (7.69%)
occurrences (all)	0	1	3
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rash vesicular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Skin hypopigmentation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypopituitarism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	4
Thyroiditis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	3
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	3 / 11 (27.27%)	4 / 13 (30.77%)
occurrences (all)	0	3	4
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	3
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	2 / 11 (18.18%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Myositis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Eye infection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hepatitis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Norovirus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vascular access site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	2 / 11 (18.18%)	4 / 13 (30.77%)
occurrences (all)	2	2	4
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	5
Electrolyte imbalance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Hypocalcaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	3 / 11 (27.27%)	1 / 13 (7.69%)
occurrences (all)	1	4	2
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Hyponatraemia			
subjects affected / exposed	2 / 6 (33.33%)	2 / 11 (18.18%)	0 / 13 (0.00%)
occurrences (all)	2	2	0
Hypovolaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 11 (9.09%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	0 / 11 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1B: BMS-986249 1200mg Q4W + Nivolumab Combination	Part 1B: BMS-986249 800mg Q4W + Nivolumab Combination	Part 1B: BMS-986249 240mg Q4W + Nivolumab Combination
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	11 / 11 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			

subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pallor			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Venous thrombosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Application site reaction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Axillary pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Complication associated with device			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Device related thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 9 (66.67%)	6 / 11 (54.55%)	9 / 12 (75.00%)
occurrences (all)	7	6	9
Hernia pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site extravasation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Localised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	2 / 9 (22.22%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	2	1	2
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Performance status decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 9 (33.33%)	4 / 11 (36.36%)	5 / 12 (41.67%)
occurrences (all)	6	5	8
Swelling face			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Xerosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Temperature intolerance subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1
Breast pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Apnoea subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	2 / 11 (18.18%) 3	2 / 12 (16.67%) 2
Dysphonia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 11 (9.09%) 1	3 / 12 (25.00%) 3
Nasal congestion			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Affective disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	3 / 12 (25.00%)
occurrences (all)	1	1	3
Depression			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Disorientation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 11 (0.00%)	2 / 12 (16.67%)
occurrences (all)	2	0	2
Libido decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Panic attack			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	1 / 11 (9.09%)	3 / 12 (25.00%)
occurrences (all)	3	2	3
Amylase increased			

subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	0	1	3
Blood albumin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	3	1	2
Blood bilirubin increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 9 (33.33%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	3	1	2
Blood calcium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Blood glucose decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood potassium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood prolactin increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood sodium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood uric acid increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	3 / 12 (25.00%)
occurrences (all)	1	0	4
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Troponin I increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine phosphorus increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine calcium increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Femur fracture			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	1 / 9 (11.11%)	2 / 11 (18.18%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Muscle strain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Lip injury			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Rib fracture			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vascular access site erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound secretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nervous system disorders			
Aphasia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cognitive disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dysarthria			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Headache			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Dysgeusia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Parkinson's disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			

subjects affected / exposed	2 / 9 (22.22%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Radiculopathy			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tension headache			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 9 (33.33%)	1 / 11 (9.09%)	6 / 12 (50.00%)
occurrences (all)	4	1	6
Eosinophilia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Hypoacusis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eyelid irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Swelling of eyelid			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	5 / 12 (41.67%)
occurrences (all)	0	1	8
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	2 / 11 (18.18%)	3 / 12 (25.00%)
occurrences (all)	0	2	3
Diarrhoea			
subjects affected / exposed	3 / 9 (33.33%)	1 / 11 (9.09%)	6 / 12 (50.00%)
occurrences (all)	6	1	12
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	1	1	0

Dysphagia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Enteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 9 (22.22%)	3 / 11 (27.27%)	6 / 12 (50.00%)
occurrences (all)	2	3	12

Oesophageal varices haemorrhage subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Oral dysaesthesia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Proctalgia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 11 (9.09%) 1	4 / 12 (33.33%) 6
Hepatobiliary disorders			
Biliary obstruction subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Autoimmune hepatitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Hepatitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Hepatic failure subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Hypertransaminasaemia			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Immune-mediated hepatitis subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Jaundice cholestatic subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Portal hypertension subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Acquired porokeratosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Drug eruption subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0

Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Keloid scar			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukoplakia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	3
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Skin hypopigmentation subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Vitiligo subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Proteinuria subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1
Haematuria subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	1 / 12 (8.33%) 1
Tubulointerstitial nephritis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 11 (9.09%) 1	1 / 12 (8.33%) 2
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1
Hyperthyroidism			

subjects affected / exposed	2 / 9 (22.22%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Hypophysitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypopituitarism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)	3 / 11 (27.27%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Back pain			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Groin pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Muscular weakness			

subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Myositis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sacral pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye infection bacterial			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatitis viral			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	2	0

Localised infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 9 (11.11%)	2 / 11 (18.18%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Norovirus infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Soft tissue infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	3	1	1

Urinary tract infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 11 (18.18%) 2	3 / 12 (25.00%) 3
Staphylococcal infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Vascular access site infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Viral infection subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	5 / 11 (45.45%) 5	3 / 12 (25.00%) 3
Dehydration subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	4 / 12 (33.33%) 5
Electrolyte imbalance subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	2 / 12 (16.67%) 3
Hypermagnesaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Hyperlipasaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Hypernatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 11 (9.09%)	5 / 12 (41.67%)
occurrences (all)	1	1	5
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Hypochloraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 11 (0.00%)	2 / 12 (16.67%)
occurrences (all)	4	0	4
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 11 (27.27%)	3 / 12 (25.00%)
occurrences (all)	0	6	5
Hypovolaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Iron deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malnutrition			

subjects affected / exposed	0 / 9 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1B: BMS-986249 1200mg Q8W+ Nivolumab Combination	Part 1B: BMS-986249 1600mg Q8W+ Nivolumab Combination	Part 2A: Melanoma Arms BMS-986249 240mg IV Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	10 / 10 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	2 / 9 (22.22%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	1 / 9 (11.11%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hypertension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pallor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Application site reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 9 (66.67%)	5 / 10 (50.00%)	0 / 3 (0.00%)
occurrences (all)	8	6	0
Hernia pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Injection site extravasation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	4 / 9 (44.44%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Swelling face			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Apnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 9 (11.11%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Dysphonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Affective disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 9 (22.22%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Libido decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental status changes			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 9 (22.22%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Amylase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 9 (33.33%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	5	3	0
Blood bilirubin increased			
subjects affected / exposed	1 / 9 (11.11%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood glucose decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood prolactin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Troponin I increased subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Transaminases increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Troponin increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Urine phosphorus increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	1 / 3 (33.33%) 1
Urine calcium increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	1 / 3 (33.33%) 1
Weight decreased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 10 (10.00%) 1	0 / 3 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 10 (10.00%) 1	0 / 3 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Femur fracture subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Infusion related reaction			

subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular access site erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound secretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	1 / 3 (33.33%) 1
Nervous system disorders			
Aphasia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Cognitive disorder subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 10 (10.00%) 1	0 / 3 (0.00%) 0
Dysarthria subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 10 (10.00%) 1	0 / 3 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	4 / 9 (44.44%) 5	1 / 10 (10.00%) 1	0 / 3 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Hyperaesthesia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Lethargy subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Neuralgia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Parkinson's disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 10 (0.00%) 0	0 / 3 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	4 / 10 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Eosinophilia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iridocyclitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid irritation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 9 (22.22%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			
subjects affected / exposed	2 / 9 (22.22%)	2 / 10 (20.00%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Colitis			

subjects affected / exposed	1 / 9 (11.11%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences (all)	3	2	2
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)	4 / 10 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	7	2
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 9 (11.11%)	3 / 10 (30.00%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Autoimmune hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypertransaminaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jaundice cholestatic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Portal hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Acquired porokeratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Drug eruption			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Keloid scar			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukoplakia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 9 (22.22%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Pruritus			
subjects affected / exposed	2 / 9 (22.22%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Rash macular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Haematuria			

subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	2 / 9 (22.22%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	2 / 9 (22.22%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hypophysitis			
subjects affected / exposed	2 / 9 (22.22%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hypopituitarism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	2 / 9 (22.22%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Thyroiditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	1 / 9 (11.11%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Groin pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypercreatinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myositis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 9 (11.11%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Candida infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	2 / 9 (22.22%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eye infection bacterial			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatitis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Soft tissue infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular access site infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 9 (11.11%)	3 / 10 (30.00%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Electrolyte imbalance			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 10 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypochloraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 10 (20.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	3 / 10 (30.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Hyponatraemia			

subjects affected / exposed	2 / 9 (22.22%)	1 / 10 (10.00%)	1 / 3 (33.33%)
occurrences (all)	3	1	1
Hypovolaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 9 (0.00%)	1 / 10 (10.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Malnutrition			
subjects affected / exposed	1 / 9 (11.11%)	0 / 10 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part 2A: Melanoma Arms BMS-986249 800mg IV Q3W	Part 2A: Melanoma Arms BMS-986249 1200mg IV Q3W	Part 2A: Melanoma Arms Ipilimumab 3mg/kg IV Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	57 / 57 (100.00%)	57 / 58 (98.28%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	5 / 58 (8.62%)
occurrences (all)	0	3	5
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	2 / 58 (3.45%)
occurrences (all)	0	2	2
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	7 / 58 (12.07%)
occurrences (all)	0	4	11
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	3 / 58 (5.17%)
occurrences (all)	0	5	4
Pallor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	13 / 57 (22.81%)	5 / 58 (8.62%)
occurrences (all)	0	15	6
Application site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	0 / 58 (0.00%)
occurrences (all)	0	3	0
Chest discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Complication associated with device			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	15 / 57 (26.32%)	19 / 58 (32.76%)
occurrences (all)	3	18	26
Hernia pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Injection site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	1 / 58 (1.72%)
occurrences (all)	0	4	1
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	5 / 58 (8.62%)
occurrences (all)	0	2	6
Malaise			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	7 / 57 (12.28%)	7 / 58 (12.07%)
occurrences (all)	0	8	8
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	14 / 57 (24.56%)	11 / 58 (18.97%)
occurrences (all)	2	23	23
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Xerosis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	8 / 58 (13.79%)
occurrences (all)	0	4	8
Temperature intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Apnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	8 / 57 (14.04%) 9	7 / 58 (12.07%) 8
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	6 / 57 (10.53%) 6	4 / 58 (6.90%) 5
Nasal congestion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	2 / 58 (3.45%) 5
Hypoxia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Haemoptysis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	0 / 58 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 57 (0.00%) 0	2 / 58 (3.45%) 5
Pleural effusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	2 / 58 (3.45%)
occurrences (all)	0	3	2
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	5 / 57 (8.77%)	3 / 58 (5.17%)
occurrences (all)	0	5	3
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Affective disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Depression			

subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences (all)	0	1	2
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	5 / 58 (8.62%)
occurrences (all)	0	3	5
Libido decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 3 (66.67%)	25 / 57 (43.86%)	22 / 58 (37.93%)
occurrences (all)	3	36	34
Amylase increased			
subjects affected / exposed	2 / 3 (66.67%)	9 / 57 (15.79%)	7 / 58 (12.07%)
occurrences (all)	2	14	11
Blood albumin decreased			
subjects affected / exposed	1 / 3 (33.33%)	4 / 57 (7.02%)	6 / 58 (10.34%)
occurrences (all)	1	5	7
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 3 (66.67%)	21 / 57 (36.84%)	25 / 58 (43.10%)
occurrences (all)	4	35	40
Blood bilirubin increased			

subjects affected / exposed	1 / 3 (33.33%)	3 / 57 (5.26%)	6 / 58 (10.34%)
occurrences (all)	2	5	8
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	7 / 58 (12.07%)
occurrences (all)	0	5	10
Blood calcium decreased			
subjects affected / exposed	1 / 3 (33.33%)	5 / 57 (8.77%)	3 / 58 (5.17%)
occurrences (all)	1	8	3
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences (all)	0	1	2
Blood cholesterol increased			
subjects affected / exposed	1 / 3 (33.33%)	5 / 57 (8.77%)	5 / 58 (8.62%)
occurrences (all)	1	10	11
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 3 (33.33%)	10 / 57 (17.54%)	10 / 58 (17.24%)
occurrences (all)	2	14	17
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	12 / 57 (21.05%)	10 / 58 (17.24%)
occurrences (all)	1	16	19
Blood glucose decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Blood lactic acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	2 / 3 (66.67%)	10 / 57 (17.54%)	10 / 58 (17.24%)
occurrences (all)	3	15	14
Blood magnesium decreased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	9 / 58 (15.52%)
occurrences (all)	0	9	13
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1

Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	1 / 58 (1.72%)
occurrences (all)	0	3	1
Blood prolactin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	1 / 3 (33.33%)	6 / 57 (10.53%)	8 / 58 (13.79%)
occurrences (all)	1	8	10
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 3 (33.33%)	9 / 57 (15.79%)	8 / 58 (13.79%)
occurrences (all)	1	10	10
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Cardiac murmur			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	7 / 57 (12.28%)	4 / 58 (6.90%)
occurrences (all)	0	7	5
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	3
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	2 / 3 (66.67%)	11 / 57 (19.30%)	13 / 58 (22.41%)
occurrences (all)	5	16	19
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	1 / 58 (1.72%)
occurrences (all)	0	3	1
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	4 / 58 (6.90%)
occurrences (all)	0	2	4
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 57 (10.53%)	5 / 58 (8.62%)
occurrences (all)	0	6	6
Urine phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Urine calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	5 / 58 (8.62%)
occurrences (all)	0	2	5
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural			

complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Vascular access site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Wound secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	5 / 57 (8.77%)	2 / 58 (3.45%)
occurrences (all)	0	5	2
Headache			
subjects affected / exposed	0 / 3 (0.00%)	10 / 57 (17.54%)	10 / 58 (17.24%)
occurrences (all)	0	11	15
Dysgeusia			

subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	2 / 58 (3.45%)
occurrences (all)	0	2	2
Parkinson's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	2
Tension headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 3 (33.33%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences (all)	1	2	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	27 / 57 (47.37%)	31 / 58 (53.45%)
occurrences (all)	3	33	48
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences (all)	0	2	2
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	2 / 58 (3.45%)
occurrences (all)	0	3	2
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Iridocyclitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Eyelid irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	4 / 58 (6.90%)
occurrences (all)	0	1	4
Swelling of eyelid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	10 / 57 (17.54%)	3 / 58 (5.17%)
occurrences (all)	1	12	4
Abdominal pain lower			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	2 / 58 (3.45%)
occurrences (all)	0	2	2
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	5 / 57 (8.77%)	1 / 58 (1.72%)
occurrences (all)	0	7	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	8 / 57 (14.04%)	9 / 58 (15.52%)
occurrences (all)	1	9	12
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	25 / 57 (43.86%)	19 / 58 (32.76%)
occurrences (all)	3	38	27
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences (all)	0	1	2
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Enteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	3 / 58 (5.17%)
occurrences (all)	0	1	3
Frequent bowel movements			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gastritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	18 / 57 (31.58%)	19 / 58 (32.76%)
occurrences (all)	2	21	29
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	3
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Stomatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	12 / 57 (21.05%)	12 / 58 (20.69%)
occurrences (all)	0	15	14
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Autoimmune hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	2 / 58 (3.45%)
occurrences (all)	0	4	2
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Hypertransaminaemia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 57 (10.53%)	1 / 58 (1.72%)
occurrences (all)	0	6	1
Immune-mediated hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	4 / 58 (6.90%)
occurrences (all)	0	0	6
Jaundice cholestatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Portal hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Acquired porokeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Drug eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	3
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	4 / 58 (6.90%)
occurrences (all)	0	1	4
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Keloid scar			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Leukoplakia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	17 / 57 (29.82%)	18 / 58 (31.03%)
occurrences (all)	1	21	21
Pruritus			

subjects affected / exposed	0 / 3 (0.00%)	22 / 57 (38.60%)	25 / 58 (43.10%)
occurrences (all)	0	28	41
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	9 / 57 (15.79%)	11 / 58 (18.97%)
occurrences (all)	0	9	13
Rash macular			
subjects affected / exposed	1 / 3 (33.33%)	3 / 57 (5.26%)	1 / 58 (1.72%)
occurrences (all)	1	3	1
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	1 / 58 (1.72%)
occurrences (all)	0	4	1
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	7 / 57 (12.28%)	7 / 58 (12.07%)
occurrences (all)	0	7	7
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	1 / 3 (33.33%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences (all)	1	2	1
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	6 / 57 (10.53%)	2 / 58 (3.45%)
occurrences (all)	0	6	2
Autoimmune thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	9 / 57 (15.79%)	12 / 58 (20.69%)
occurrences (all)	0	10	12
Hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Hypopituitarism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	13 / 57 (22.81%)	12 / 58 (20.69%)
occurrences (all)	0	16	13
Thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0

Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 3 (66.67%)	15 / 57 (26.32%)	10 / 58 (17.24%)
occurrences (all)	2	16	15
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	9 / 57 (15.79%)	6 / 58 (10.34%)
occurrences (all)	0	9	6
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Hypercreatinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	4 / 58 (6.90%)
occurrences (all)	0	0	4
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	5 / 58 (8.62%)
occurrences (all)	0	4	5
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	4 / 58 (6.90%)
occurrences (all)	0	4	6
Sacral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Campylobacter infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	4 / 57 (7.02%)	2 / 58 (3.45%)
occurrences (all)	0	4	2
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Eye infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Hepatitis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Mucosal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	2 / 58 (3.45%)
occurrences (all)	0	2	2
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Norovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Rash pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	4 / 58 (6.90%)
occurrences (all)	0	1	4
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	6 / 57 (10.53%)	6 / 58 (10.34%)
occurrences (all)	1	8	7
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Vascular access site infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 3 (0.00%)	10 / 57 (17.54%)	17 / 58 (29.31%)
occurrences (all)	0	11	18
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	3 / 57 (5.26%)	2 / 58 (3.45%)
occurrences (all)	0	3	2
Electrolyte imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 3 (33.33%)	5 / 57 (8.77%)	4 / 58 (6.90%)
occurrences (all)	1	6	5
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences (all)	0	1	2
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 57 (3.51%)	0 / 58 (0.00%)
occurrences (all)	0	3	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	3 / 58 (5.17%)
occurrences (all)	0	1	7
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 57 (1.75%)	2 / 58 (3.45%)
occurrences (all)	0	1	3
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	11 / 57 (19.30%)	16 / 58 (27.59%)
occurrences (all)	4	19	30
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2A: Melanoma Arms Nivolumab Mono	Part 2A: Melanoma Arms BMS-986249 600mg IV Q8W	Part 2B: Cohort 1 (HCC)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	34 / 36 (94.44%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cancer pain			

subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	4 / 36 (11.11%)	0 / 5 (0.00%)
occurrences (all)	1	4	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Pallor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	1	3	0
Application site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Complication associated with device			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	9 / 36 (25.00%)	4 / 5 (80.00%)
occurrences (all)	0	11	4
Hernia pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	2 / 5 (40.00%)
occurrences (all)	0	2	2
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	1 / 5 (20.00%)
occurrences (all)	0	5	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	8 / 36 (22.22%)	3 / 5 (60.00%)
occurrences (all)	0	15	4
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	1 / 3 (33.33%)	4 / 36 (11.11%)	0 / 5 (0.00%)
occurrences (all)	1	4	0

Temperature intolerance subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all) Breast pain subjects affected / exposed occurrences (all) Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 36 (0.00%) 0 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Apnoea subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Dysphonia subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Hypoxia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 36 (0.00%) 0 4 / 36 (11.11%) 6 0 / 36 (0.00%) 0 3 / 36 (8.33%) 3 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0

Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Affective disorder			

subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Libido decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	14 / 36 (38.89%)	2 / 5 (40.00%)
occurrences (all)	1	21	2
Amylase increased			
subjects affected / exposed	2 / 3 (66.67%)	6 / 36 (16.67%)	0 / 5 (0.00%)
occurrences (all)	2	11	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	10 / 36 (27.78%)	2 / 5 (40.00%)
occurrences (all)	0	12	2
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	2 / 5 (40.00%)
occurrences (all)	5	3	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	1	3	0
Blood cholesterol increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	1 / 5 (20.00%)
occurrences (all)	0	4	1
Blood glucose decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Blood magnesium decreased			

subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Blood prolactin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 3 (33.33%)	7 / 36 (19.44%)	0 / 5 (0.00%)
occurrences (all)	5	10	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Urine phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urine calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	8 / 36 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	9	0

White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular access site erythema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	5 / 36 (13.89%)	2 / 5 (40.00%)
occurrences (all)	0	5	2
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parkinson's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	13 / 36 (36.11%)	1 / 5 (20.00%)
occurrences (all)	2	19	1
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Thrombocytopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1

Neutropenia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 36 (5.56%) 2	0 / 5 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Hypoacusis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 36 (2.78%) 1	0 / 5 (0.00%) 0
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Iridocyclitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Eyelid irritation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Swelling of eyelid subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 36 (2.78%) 1	0 / 5 (0.00%) 0
Abdominal pain			

subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	1 / 5 (20.00%)
occurrences (all)	0	4	2
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	5 / 36 (13.89%)	1 / 5 (20.00%)
occurrences (all)	2	6	1
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	15 / 36 (41.67%)	2 / 5 (40.00%)
occurrences (all)	1	33	4
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Frequent bowel movements			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	9 / 36 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	11	1
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 36 (5.56%) 3	1 / 5 (20.00%) 1
Vomiting subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	7 / 36 (19.44%) 9	0 / 5 (0.00%) 0
Hepatobiliary disorders Biliary obstruction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Autoimmune hepatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 36 (2.78%) 1	0 / 5 (0.00%) 0
Hepatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 36 (5.56%) 4	0 / 5 (0.00%) 0
Hepatic failure subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Hypertransaminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	5 / 36 (13.89%) 5	0 / 5 (0.00%) 0
Immune-mediated hepatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Jaundice cholestatic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0
Portal hypertension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 36 (0.00%) 0	0 / 5 (0.00%) 0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Acquired porokeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	1 / 5 (20.00%)
occurrences (all)	0	4	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Keloid scar			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Leukoplakia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	1 / 3 (33.33%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	10 / 36 (27.78%)	1 / 5 (20.00%)
occurrences (all)	2	11	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	6 / 36 (16.67%)	2 / 5 (40.00%)
occurrences (all)	0	7	2
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	1 / 3 (33.33%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	1 / 5 (20.00%)
occurrences (all)	0	4	1

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 3 (33.33%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Hypophysitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	1 / 5 (20.00%)
occurrences (all)	0	3	1
Hypopituitarism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	8 / 36 (22.22%)	1 / 5 (20.00%)
occurrences (all)	0	8	1
Thyroiditis			

subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	5 / 36 (13.89%)	0 / 5 (0.00%)
occurrences (all)	1	6	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercreatinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	8 / 36 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	9	0
Myositis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	1 / 5 (20.00%)
occurrences (all)	0	4	1
Sacral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Campylobacter infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	7 / 36 (19.44%)	0 / 5 (0.00%)
occurrences (all)	0	7	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Eye infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hepatitis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0

Norovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 36 (5.56%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Soft tissue infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	3 / 36 (8.33%)	1 / 5 (20.00%)
occurrences (all)	0	4	2
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular access site infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	7 / 36 (19.44%)	1 / 5 (20.00%)
occurrences (all)	0	7	1
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	4 / 36 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	5	0
Electrolyte imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypochloraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 36 (8.33%)	1 / 5 (20.00%)
occurrences (all)	4	4	2
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 36 (2.78%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 36 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2B: Cohort 2 (Metastatic CRPC)	Part 2B: Cohort 3 (Unresectable TNBC)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 41 (95.12%)	45 / 45 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Malignant neoplasm progression			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Cancer pain			
subjects affected / exposed	2 / 41 (4.88%)	2 / 45 (4.44%)	
occurrences (all)	2	3	
Tumour pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Metastases to central nervous system			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Haematoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Haemorrhage			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	5 / 41 (12.20%)	2 / 45 (4.44%)	
occurrences (all)	5	2	
Hypotension			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Pallor			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Venous thrombosis			

subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 41 (7.32%)	7 / 45 (15.56%)	
occurrences (all)	3	7	
Application site reaction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Axillary pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Chest discomfort			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Chest pain			
subjects affected / exposed	0 / 41 (0.00%)	3 / 45 (6.67%)	
occurrences (all)	0	3	
Chills			
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)	
occurrences (all)	0	2	
Complication associated with device			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Device related thrombosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	18 / 41 (43.90%)	13 / 45 (28.89%)	
occurrences (all)	21	17	
Hernia pain			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Injection site extravasation		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Influenza like illness		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Localised oedema		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Mucosal inflammation		
subjects affected / exposed	2 / 41 (4.88%)	3 / 45 (6.67%)
occurrences (all)	2	3
Malaise		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Non-cardiac chest pain		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Oedema peripheral		
subjects affected / exposed	9 / 41 (21.95%)	3 / 45 (6.67%)
occurrences (all)	9	3
Pain		
subjects affected / exposed	3 / 41 (7.32%)	2 / 45 (4.44%)
occurrences (all)	3	2
Performance status decreased		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Peripheral swelling		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Pyrexia		
subjects affected / exposed	3 / 41 (7.32%)	14 / 45 (31.11%)
occurrences (all)	3	19
Swelling face		

subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Xerosis subjects affected / exposed occurrences (all)	9 / 41 (21.95%) 9	3 / 45 (6.67%) 3	
Temperature intolerance subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Breast pain subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	1 / 45 (2.22%) 1	
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Apnoea subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Cough subjects affected / exposed occurrences (all)	11 / 41 (26.83%) 12	13 / 45 (28.89%) 14	
Dysphonia subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	1 / 45 (2.22%) 1	
Dyspnoea subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1	8 / 45 (17.78%) 9	
Nasal congestion			

subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Hypoxia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Pleural effusion			
subjects affected / exposed	0 / 41 (0.00%)	4 / 45 (8.89%)	
occurrences (all)	0	4	
Pneumonitis			
subjects affected / exposed	2 / 41 (4.88%)	3 / 45 (6.67%)	
occurrences (all)	4	4	
Pneumothorax			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Rhinitis allergic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			

Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Affective disorder			
subjects affected / exposed	3 / 41 (7.32%)	0 / 45 (0.00%)	
occurrences (all)	3	0	
Anxiety			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Disorientation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	5 / 41 (12.20%)	3 / 45 (6.67%)	
occurrences (all)	5	4	
Libido decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Mental status changes			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Panic attack			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	10 / 41 (24.39%)	16 / 45 (35.56%)	
occurrences (all)	13	25	
Amylase increased			

subjects affected / exposed	1 / 41 (2.44%)	10 / 45 (22.22%)
occurrences (all)	1	10
Blood albumin decreased		
subjects affected / exposed	4 / 41 (9.76%)	7 / 45 (15.56%)
occurrences (all)	8	9
Aspartate aminotransferase increased		
subjects affected / exposed	8 / 41 (19.51%)	17 / 45 (37.78%)
occurrences (all)	12	28
Blood bilirubin increased		
subjects affected / exposed	3 / 41 (7.32%)	4 / 45 (8.89%)
occurrences (all)	3	4
Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)
occurrences (all)	1	2
Blood calcium decreased		
subjects affected / exposed	4 / 41 (9.76%)	1 / 45 (2.22%)
occurrences (all)	13	1
Blood calcium increased		
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	1
Blood cholesterol increased		
subjects affected / exposed	2 / 41 (4.88%)	6 / 45 (13.33%)
occurrences (all)	2	7
Blood creatine phosphokinase increased		
subjects affected / exposed	2 / 41 (4.88%)	5 / 45 (11.11%)
occurrences (all)	3	7
Blood creatinine increased		
subjects affected / exposed	4 / 41 (9.76%)	1 / 45 (2.22%)
occurrences (all)	5	1
Blood glucose decreased		
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	1
Blood lactic acid increased		

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Blood glucose increased		
subjects affected / exposed	3 / 41 (7.32%)	5 / 45 (11.11%)
occurrences (all)	3	10
Blood magnesium decreased		
subjects affected / exposed	2 / 41 (4.88%)	10 / 45 (22.22%)
occurrences (all)	2	12
Blood phosphorus increased		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Blood potassium decreased		
subjects affected / exposed	3 / 41 (7.32%)	1 / 45 (2.22%)
occurrences (all)	3	1
Blood prolactin increased		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Blood sodium decreased		
subjects affected / exposed	7 / 41 (17.07%)	5 / 45 (11.11%)
occurrences (all)	11	6
Blood thyroid stimulating hormone decreased		
subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)
occurrences (all)	1	2
Blood thyroid stimulating hormone increased		
subjects affected / exposed	2 / 41 (4.88%)	6 / 45 (13.33%)
occurrences (all)	2	6
Blood uric acid increased		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
C-reactive protein increased		
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	1
Cardiac murmur		

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 41 (2.44%)	6 / 45 (13.33%)	
occurrences (all)	1	6	
Haemoglobin decreased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
International normalised ratio increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	5 / 41 (12.20%)	8 / 45 (17.78%)	
occurrences (all)	6	9	
Liver function test increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	1 / 41 (2.44%)	3 / 45 (6.67%)	
occurrences (all)	1	6	
Platelet count decreased			
subjects affected / exposed	2 / 41 (4.88%)	5 / 45 (11.11%)	
occurrences (all)	2	6	
Troponin I increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Transaminases increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Troponin increased			
subjects affected / exposed	4 / 41 (9.76%)	2 / 45 (4.44%)	
occurrences (all)	5	2	
Urine phosphorus increased			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Urine calcium increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	13 / 41 (31.71%)	5 / 45 (11.11%)	
occurrences (all)	14	5	
White blood cell count decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
White blood cell count increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Femur fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Muscle strain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Lip injury			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Rib fracture			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Skin abrasion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Vascular access site erythema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Wound secretion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Palpitations			
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Pericardial effusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Sinus bradycardia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	3 / 41 (7.32%)	3 / 45 (6.67%)	
occurrences (all)	4	3	
Tachycardia			
subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)	
occurrences (all)	1	2	
Nervous system disorders			
Aphasia			

subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)
occurrences (all)	1	0
Cognitive disorder		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Dysarthria		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Dizziness		
subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)
occurrences (all)	1	3
Headache		
subjects affected / exposed	1 / 41 (2.44%)	9 / 45 (20.00%)
occurrences (all)	1	10
Dysgeusia		
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)
occurrences (all)	2	1
Hyperaesthesia		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Lethargy		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Neuralgia		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Neuropathy peripheral		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Paraesthesia		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Parkinson's disease		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Peripheral sensory neuropathy		

subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Peripheral motor neuropathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Post herpetic neuralgia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Restless legs syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Radiculopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Tension headache			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	21 / 41 (51.22%)	23 / 45 (51.11%)	
occurrences (all)	35	32	
Eosinophilia			
subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)	
occurrences (all)	2	2	
Iron deficiency anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	

Leukocytosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Thrombocytopenia			
subjects affected / exposed	4 / 41 (9.76%)	3 / 45 (6.67%)	
occurrences (all)	4	3	
Neutropenia			
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)	
occurrences (all)	2	2	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Hypoacusis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)	
occurrences (all)	0	2	
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 41 (2.44%)	1 / 45 (2.22%)	
occurrences (all)	1	1	
Iridocyclitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Eyelid irritation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Swelling of eyelid			

subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	3 / 41 (7.32%)	8 / 45 (17.78%)	
occurrences (all)	3	8	
Abdominal pain lower			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 41 (0.00%)	3 / 45 (6.67%)	
occurrences (all)	0	5	
Ascites			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Colitis			
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Constipation			
subjects affected / exposed	6 / 41 (14.63%)	4 / 45 (8.89%)	
occurrences (all)	8	4	
Diarrhoea			
subjects affected / exposed	19 / 41 (46.34%)	19 / 45 (42.22%)	
occurrences (all)	28	26	
Dyspepsia			
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)	
occurrences (all)	0	3	
Dry mouth			
subjects affected / exposed	3 / 41 (7.32%)	0 / 45 (0.00%)	
occurrences (all)	3	0	

Dysphagia		
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)
occurrences (all)	2	1
Enteritis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Flatulence		
subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)
occurrences (all)	2	2
Frequent bowel movements		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Gastritis		
subjects affected / exposed	1 / 41 (2.44%)	1 / 45 (2.22%)
occurrences (all)	1	1
Gastrointestinal motility disorder		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Immune-mediated enterocolitis		
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)
occurrences (all)	2	0
Impaired gastric emptying		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Mouth ulceration		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Nausea		
subjects affected / exposed	12 / 41 (29.27%)	13 / 45 (28.89%)
occurrences (all)	13	16

Oesophageal varices haemorrhage subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Oral dysaesthesia subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Proctalgia subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Stomatitis subjects affected / exposed occurrences (all)	2 / 41 (4.88%) 2	3 / 45 (6.67%) 5	
Vomiting subjects affected / exposed occurrences (all)	3 / 41 (7.32%) 5	11 / 45 (24.44%) 13	
Hepatobiliary disorders			
Biliary obstruction subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Autoimmune hepatitis subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Hepatitis subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	1 / 45 (2.22%) 1	
Hepatic failure subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Hypertransaminasaemia			

subjects affected / exposed	1 / 41 (2.44%)	2 / 45 (4.44%)	
occurrences (all)	1	2	
Immune-mediated hepatitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Jaundice cholestatic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Portal hypertension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Acquired porokeratosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Dermatitis acneiform			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Drug eruption			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Ecchymosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	

Night sweats			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Keloid scar			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Leukoplakia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	6 / 41 (14.63%)	7 / 45 (15.56%)	
occurrences (all)	7	8	
Pruritus			
subjects affected / exposed	16 / 41 (39.02%)	12 / 45 (26.67%)	
occurrences (all)	17	16	
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	3 / 41 (7.32%)	4 / 45 (8.89%)	
occurrences (all)	3	4	
Rash macular			
subjects affected / exposed	1 / 41 (2.44%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Rash erythematous			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Rash vesicular			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Transient acantholytic dermatosis			

subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Skin hypopigmentation subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Urticaria subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1	0 / 45 (0.00%) 0	
Vitiligo subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Pollakiuria subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Proteinuria subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	1 / 45 (2.22%) 1	
Haematuria subjects affected / exposed occurrences (all)	2 / 41 (4.88%) 2	0 / 45 (0.00%) 0	
Tubulointerstitial nephritis subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1	0 / 45 (0.00%) 0	
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	5 / 41 (12.20%) 5	2 / 45 (4.44%) 2	
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Hyperthyroidism			

subjects affected / exposed	5 / 41 (12.20%)	4 / 45 (8.89%)	
occurrences (all)	5	4	
Hypophysitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Hypopituitarism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	4 / 41 (9.76%)	8 / 45 (17.78%)	
occurrences (all)	4	8	
Thyroiditis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 41 (14.63%)	12 / 45 (26.67%)	
occurrences (all)	7	12	
Back pain			
subjects affected / exposed	4 / 41 (9.76%)	2 / 45 (4.44%)	
occurrences (all)	5	2	
Groin pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Hypercreatinaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			

subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Muscle spasms			
subjects affected / exposed	3 / 41 (7.32%)	3 / 45 (6.67%)	
occurrences (all)	3	3	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)	
occurrences (all)	0	2	
Myalgia			
subjects affected / exposed	5 / 41 (12.20%)	6 / 45 (13.33%)	
occurrences (all)	5	8	
Myositis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Neck pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	2 / 41 (4.88%)	2 / 45 (4.44%)	
occurrences (all)	2	2	
Sacral pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 41 (7.32%)	2 / 45 (4.44%)	
occurrences (all)	4	2	
Campylobacter infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Candida infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	

Cellulitis		
subjects affected / exposed	0 / 41 (0.00%)	2 / 45 (4.44%)
occurrences (all)	0	2
Conjunctivitis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Cystitis		
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)
occurrences (all)	1	0
Diverticulitis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Eye infection bacterial		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Folliculitis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Gastroenteritis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Hepatitis viral		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Gastrointestinal infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Herpes zoster		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Hordeolum		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Influenza		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0

Localised infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Mucosal infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Nasopharyngitis		
subjects affected / exposed	2 / 41 (4.88%)	0 / 45 (0.00%)
occurrences (all)	2	0
Oral candidiasis		
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	1
Norovirus infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Pharyngitis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Rash pustular		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Pneumonia		
subjects affected / exposed	5 / 41 (12.20%)	1 / 45 (2.22%)
occurrences (all)	6	1
Soft tissue infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Skin infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Spontaneous bacterial peritonitis		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Upper respiratory tract infection		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0

Urinary tract infection subjects affected / exposed occurrences (all)	6 / 41 (14.63%) 7	8 / 45 (17.78%) 12	
Staphylococcal infection subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Vascular access site infection subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Viral infection subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	16 / 41 (39.02%) 16	13 / 45 (28.89%) 14	
Dehydration subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1	1 / 45 (2.22%) 1	
Electrolyte imbalance subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Hyperglycaemia subjects affected / exposed occurrences (all)	3 / 41 (7.32%) 3	5 / 45 (11.11%) 9	
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	1 / 45 (2.22%) 1	
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1	0 / 45 (0.00%) 0	
Hypermagnesaemia subjects affected / exposed occurrences (all)	0 / 41 (0.00%) 0	0 / 45 (0.00%) 0	
Hyperlipasaemia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Hyperuricaemia		
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)
occurrences (all)	1	0
Hypernatraemia		
subjects affected / exposed	0 / 41 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	1
Hypoalbuminaemia		
subjects affected / exposed	1 / 41 (2.44%)	1 / 45 (2.22%)
occurrences (all)	1	2
Hypocalcaemia		
subjects affected / exposed	2 / 41 (4.88%)	1 / 45 (2.22%)
occurrences (all)	3	1
Hypochloraemia		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Hypokalaemia		
subjects affected / exposed	3 / 41 (7.32%)	1 / 45 (2.22%)
occurrences (all)	5	1
Hypomagnesaemia		
subjects affected / exposed	2 / 41 (4.88%)	3 / 45 (6.67%)
occurrences (all)	2	3
Hyponatraemia		
subjects affected / exposed	7 / 41 (17.07%)	4 / 45 (8.89%)
occurrences (all)	9	5
Hypovolaemia		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Hypophosphataemia		
subjects affected / exposed	1 / 41 (2.44%)	0 / 45 (0.00%)
occurrences (all)	1	0
Iron deficiency		
subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0
Malnutrition		

subjects affected / exposed	0 / 41 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 November 2017	Includes responses to FDA questions about bladder and breast cancer population inclusion criteria, DLT criteria including ocular events, discontinuation from study treatment, clarification of expression of some tumor markers, updated imaging, biopsy and infusion time language.
24 January 2018	Expand Part 1B tumor types, clarify the change in frequency of scans up to Week 48 versus thereafter, add co-administration of BMS-986249 + nivolumab in Part 1B, update 2 year treatment duration, add PCWG3 for prostate cancer, and minor typographical updates were made for consistency and clarity of the words participants, patients, and subjects.
25 May 2018	Change dose-limiting toxicity evaluation period, change Parts 1A and 1B treatment assignments, provide a window for clinic visits, incorporate Administrative Letter 01, and minor typographical updates were made for consistency and clarity.
01 March 2019	This is a revised protocol to define the Part 2A Expansion Phase, which includes concurrent evaluation of three different dose regimens of BMS-986249 in combination with nivolumab in relation to two standard of care reference arms in a randomized setting in melanoma. This protocol revision also updates DLT criteria, updates inclusion/exclusion criteria, changes the on-treatment biopsy timing, and provides clarifications around planned dose level modifications/intermediate dose levels, and incorporates other clarifying modifications.
01 May 2019	This is a revised protocol to explicitly mention encephalitis as an example of a possible neurological adverse event, updates management algorithms for immuno-oncology agents, updates PD-L1 stratification criteria for Part 2A, clarifies screening biopsy criteria for Part 2A, and incorporates other clarifying modifications.
05 August 2019	This is a revised protocol that defines the selected BMS-986249 + nivolumab doses and schedules for Part 2A Arms A - C, updates modified intermediate dose levels in Part 1B, and incorporates other minor clarifying edits.
15 November 2020	This is a revised protocol to modify the treatment arms in the Part 2A Expansion Phase and define the Part 2B Expansion Phase. The Part 2A Expansion Phase will now include concurrent evaluation of 3 treatment arms in a randomized setting in melanoma (2 different dose regimens of BMS-986249 in combination with nivolumab and 1 standard-of-care reference arm) rather than the previously defined 5 treatment arms. The Part 2B Expansion Phase will evaluate a single-dose regimen of BMS-986248 in combination with nivolumab in 3 tumor-specific cohorts. This revision also includes global changes to reduce redundancies and increase readability, incorporates updated learnings for BMS-986249, nivolumab, and ipilimumab, and adds language around COVID-19.
22 February 2022	The primary reasons for Protocol Amendment 08 are to update and/or clarify the inclusion criteria to align with the current disease state and treatment landscape based on investigator feedback for Part 2.

14 March 2023	The overall rationale for this protocol amendment is to remove exploratory endpoints (modified RECIST version 1.1 for immune-based therapeutics [iRECIST] and severe acute respiratory syndrome coronavirus 2 [SARSCoV-2]); to introduce the option of also supplying sites with 10-mL vials containing 50 mg of ipilimumab; to decrease participant and site burden by reducing pharmacokinetic (PK), anti-drug antibody (ADA), and biomarker sample collections; and to add clarifying language.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported