Clinical trial results:
A Phase 1/2a Dose Escalation and Cohort Expansion Study for Safety, Tolerability, and Efficacy of BMS-986156 Administered Alone and in Combination with Nivolumab (BMS-936558, anti PD-1 Monoclonal Antibody) in Advanced Solid Tumors

Summary

EudraCT number	2015-002505-11
Trial protocol	NL BE ES DE FR IT
Global end of trial date	28 August 2019

Results information

Result version number	v1 (current)
This version publication date	05 January 2023
First version publication date	05 January 2023
Summary attachment (see zip file)	Delayed Results Explanation (CA009-002 EudraCT letter for delayed results_19jul2021.pdf)

Trial information

Trial identification

Sponsor protocol code	CA009-002

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 International Corporation, EU Study Start-Up Unit, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@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	28 August 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 August 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to determine the safety, tolerability, dose-limiting toxicities (DLTs), and MTD/MAD/alternate dose(s) of BMS-986156 administered alone and in combination with nivolumab in subjects with advanced solid tumors.

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	09 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 4
Country: Number of subjects enrolled	Australia: 61
Country: Number of subjects enrolled	Canada: 35
Country: Number of subjects enrolled	France: 30
Country: Number of subjects enrolled	Germany: 7
Country: Number of subjects enrolled	Italy: 22
Country: Number of subjects enrolled	Netherlands: 38
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	Switzerland: 28
Country: Number of subjects enrolled	United States: 28
Country: Number of subjects enrolled	Belgium: 14
Worldwide total number of subjects	292
EEA total number of subjects	140

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)	196
From 65 to 84 years	95
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
292 subjects randomized and treated

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: BMS-986156 10mg

Arm description:
BMS-986156 10mg Q2W

Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 A: BMS-986156 30mg

Arm description:
BMS-986156 30mg Q2W

Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 A: BMS-986156 100mg

Arm description:
BMS-986156 100mg Q2W

Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 A: BMS-986156 240mg

Arm description: BMS-986156 240mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 A: BMS-986156 800mg
Arm description: BMS-986156 800mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 C: BMS-986156 240mg
Arm description: BMS-986156 240mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 C: BMS-986156 800mg
Arm description: BMS-986156 800mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS-986156
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 B: BMS-986156 30mg + Nivo 240mg
Arm description: BMS986156 30mg Q2W + Nivo 240mg Q2W	
Arm type	Experimental

Investigational medicinal product name	BMS-986156
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	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 B: BMS-986156 100mg + Nivo 240mg
Arm description: BMS986156 100mg Q2W + Nivo 240mg Q2W	
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-986156
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 B: BMS-986156 240mg + Nivo 240mg
Arm description: BMS986156 240mg Q2W + Nivo 240mg Q2W	
Arm type	Experimental
Investigational medicinal product name	BMS-986156
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	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 B: BMS-986156 800mg + Nivo 240mg

Arm description: BMS986156 800mg Q2W + Nivo 240mg Q2W	
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-986156
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 D: BMS-986156 240mg + Nivo 240mg
Arm description: BMS986156 240mg Q2W + Nivo 240mg Q2W	
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-986156
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 E: BMS-986156 480mg + Nivo 480mg
Arm description: BMS986156 480mg Q4W + Nivo 480mg Q4W	
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-986156
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
100mg/vial (10mg/mL)

Number of subjects in period 1	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg
Started	4	6	4
Completed	0	0	0
Not completed	4	6	4
Adverse Event unrelated to study drug	-	1	-
Study drug toxicity	-	-	-
Other Reasons	-	-	-
No longer meets study criteria	-	-	-
Disease Progression	4	4	4
participant request to discontinue	-	1	-
participant withdrew consent	-	-	-

Number of subjects in period 1	Part A: BMS-986156 240mg	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg
Started	6	9	3
Completed	0	0	1
Not completed	6	9	2
Adverse Event unrelated to study drug	-	-	-
Study drug toxicity	-	-	-
Other Reasons	-	-	-
No longer meets study criteria	-	-	-
Disease Progression	6	8	2
participant request to discontinue	-	1	-
participant withdrew consent	-	-	-

Number of subjects in period 1	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg	Part B: BMS-986156 100mg + Nivo 240mg
Started	2	3	9
Completed	0	0	2
Not completed	2	3	7
Adverse Event unrelated to study drug	-	-	-
Study drug toxicity	-	-	-
Other Reasons	-	-	-

No longer meets study criteria	-	-	-
Disease Progression	2	3	7
participant request to discontinue	-	-	-
participant withdrew consent	-	-	-

Number of subjects in period 1	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Started	14	11	188
Completed	3	3	23
Not completed	11	8	165
Adverse Event unrelated to study drug	1	-	11
Study drug toxicity	1	-	3
Other Reasons	-	-	-
No longer meets study criteria	-	-	1
Disease Progression	9	7	143
participant request to discontinue	-	1	4
participant withdrew consent	-	-	3

Number of subjects in period 1	Part E: BMS-986156 480mg + Nivo 480mg
Started	33
Completed	7
Not completed	26
Adverse Event unrelated to study drug	2
Study drug toxicity	-
Other Reasons	1
No longer meets study criteria	-
Disease Progression	23
participant request to discontinue	-
participant withdrew consent	-

Baseline characteristics

Reporting groups	
Reporting group title	Part A: BMS-986156 10mg
Reporting group description: BMS-986156 10mg Q2W	
Reporting group title	Part A: BMS-986156 30mg
Reporting group description: BMS-986156 30mg Q2W	
Reporting group title	Part A: BMS-986156 100mg
Reporting group description: BMS-986156 100mg Q2W	
Reporting group title	Part A: BMS-986156 240mg
Reporting group description: BMS-986156 240mg Q2W	
Reporting group title	Part A: BMS-986156 800mg
Reporting group description: BMS-986156 800mg Q2W	
Reporting group title	Part C: BMS-986156 240mg
Reporting group description: BMS-986156 240mg Q2W	
Reporting group title	Part C: BMS-986156 800mg
Reporting group description: BMS-986156 800mg Q2W	
Reporting group title	Part B: BMS-986156 30mg + Nivo 240mg
Reporting group description: BMS986156 30mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 100mg + Nivo 240mg
Reporting group description: BMS986156 100mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 240mg + Nivo 240mg
Reporting group description: BMS986156 240mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 800mg + Nivo 240mg
Reporting group description: BMS986156 800mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part D: BMS-986156 240mg + Nivo 240mg
Reporting group description: BMS986156 240mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part E: BMS-986156 480mg + Nivo 480mg
Reporting group description: BMS986156 480mg Q4W + Nivo 480mg Q4W	

Reporting group values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg
Number of subjects	4	6	4
Age categorical Units: Subjects			
Adults (18-64 years)	2	5	3
From 65-84 years	2	1	1

85 years and over	0	0	0

Age Continuous			
Units: Years			
arithmetic mean	55.3	59.7	57.4
standard deviation	± 18.57	± 5.82	± 10.08
Sex: Female, Male			
Units: Participants			
Female	4	1	1
Male	0	5	3
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	0
White	3	6	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	4	6	1
Unknown or Not Reported	0	0	1

Reporting group values	Part A: BMS-986156 240mg	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg
Number of subjects	6	9	3
Age categorical			
Units: Subjects			
Adults (18-64 years)	5	7	2
From 65-84 years	1	2	1
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	49.5	51.0	58.3
standard deviation	± 13.28	± 13.82	± 19.43
Sex: Female, Male			
Units: Participants			
Female	3	5	1
Male	3	4	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	8	3
More than one race	0	0	0

Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	5	1
Unknown or Not Reported	3	4	2

Reporting group values	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg	Part B: BMS-986156 100mg + Nivo 240mg
Number of subjects	2	3	9
Age categorical Units: Subjects			
Adults (18-64 years)	1	3	6
From 65-84 years	1	0	3
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	56.5	50.7	57.2
standard deviation	± 9.19	± 20.50	± 12.09
Sex: Female, Male Units: Participants			
Female	1	2	4
Male	1	1	5
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	0	0	0
White	2	3	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	2	6
Unknown or Not Reported	2	1	3

Reporting group values	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Number of subjects	14	11	188
Age categorical Units: Subjects			
Adults (18-64 years)	9	9	124
From 65-84 years	4	2	64
85 years and over	1	0	0
Age Continuous Units: Years			
arithmetic mean	55.6	57.0	59.0
standard deviation	± 18.67	± 9.30	± 11.58

Sex: Female, Male Units: Participants			
Female	5	7	100
Male	9	4	88
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	0	13
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	2
White	12	11	171
More than one race	0	0	0
Unknown or Not Reported	0	0	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	7	4	51
Unknown or Not Reported	7	7	136

Reporting group values	Part E: BMS-986156 480mg + Nivo 480mg	Total	
Number of subjects	33	292	
Age categorical Units: Subjects			
Adults (18-64 years)	19	195	
From 65-84 years	14	96	
85 years and over	0	1	
Age Continuous Units: Years			
arithmetic mean	57.2		
standard deviation	± 13.05	-	
Sex: Female, Male Units: Participants			
Female	22	156	
Male	11	136	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	5	24	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	3	
White	27	262	
More than one race	0	0	
Unknown or Not Reported	1	3	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	4	
Not Hispanic or Latino	11	101	
Unknown or Not Reported	21	187	

End points

End points reporting groups

Reporting group title	Part A: BMS-986156 10mg
Reporting group description: BMS-986156 10mg Q2W	
Reporting group title	Part A: BMS-986156 30mg
Reporting group description: BMS-986156 30mg Q2W	
Reporting group title	Part A: BMS-986156 100mg
Reporting group description: BMS-986156 100mg Q2W	
Reporting group title	Part A: BMS-986156 240mg
Reporting group description: BMS-986156 240mg Q2W	
Reporting group title	Part A: BMS-986156 800mg
Reporting group description: BMS-986156 800mg Q2W	
Reporting group title	Part C: BMS-986156 240mg
Reporting group description: BMS-986156 240mg Q2W	
Reporting group title	Part C: BMS-986156 800mg
Reporting group description: BMS-986156 800mg Q2W	
Reporting group title	Part B: BMS-986156 30mg + Nivo 240mg
Reporting group description: BMS986156 30mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 100mg + Nivo 240mg
Reporting group description: BMS986156 100mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 240mg + Nivo 240mg
Reporting group description: BMS986156 240mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 800mg + Nivo 240mg
Reporting group description: BMS986156 800mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part D: BMS-986156 240mg + Nivo 240mg
Reporting group description: BMS986156 240mg Q2W + Nivo 240mg Q2W	
Reporting group title	Part E: BMS-986156 480mg + Nivo 480mg
Reporting group description: BMS986156 480mg Q4W + Nivo 480mg Q4W	

Primary: Number of participants with all cause adverse events (AEs), serious adverse events, AEs leading to discontinuation and deaths.

End point title	Number of participants with all cause adverse events (AEs), serious adverse events, AEs leading to discontinuation and deaths.[1]

End point description:

Number of participants with all cause adverse events (AEs), serious adverse events (SAEs), adverse events leading to discontinuation, and number of participant deaths.

End point type	Primary

End point timeframe:

Approximately up to 29 months

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 statistical analysis done for this endpoint

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Participants				
Adverse Events (AEs)	4	6	4	6
Serious Adverse Events (SAEs)	3	3	1	5
AEs leading to Discontinuation	1	2	0	2
Deaths	4	5	3	5

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3
Units: Participants				
Adverse Events (AEs)	9	3	2	3
Serious Adverse Events (SAEs)	4	2	2	2
AEs leading to Discontinuation	1	0	0	0
Deaths	6	2	2	3

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	11	188
Units: Participants				
Adverse Events (AEs)	9	14	11	188
Serious Adverse Events (SAEs)	5	10	6	121
AEs leading to Discontinuation	1	2	1	32
Deaths	6	11	8	141

End point values	Part E: BMS-986156 480mg + Nivo 480mg			

Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Participants				
Adverse Events (AEs)	33			
Serious Adverse Events (SAEs)	22			
AEs leading to Discontinuation	5			
Deaths	27			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with laboratory abnormalities in specific thyroid tests

End point title	Number of Participants with laboratory abnormalities in specific thyroid tests[2]

End point description:

Number of Participants with laboratory abnormalities in specific thyroid tests.

TSH = Thyroid stimulating hormone
ULN = Upper limit number
LLN = Lower limit number

End point type	Primary

End point timeframe:

Approximately up to 29 months

Notes:

[2] - 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 statistical analysis done for this endpoint

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Participants				
TSH > ULN	1	2	0	2
TSH > ULN WITH TSH ≤ ULN AT BASELINE	0	0	0	0
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0	0	0	0
TSH < LLN	0	0	0	0
TSH <LLN WITH TSH ≥ LLN AT BASELINE	0	0	0	0
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	0	1	0

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3

Units: Participants				
TSH > ULN	2	0	0	1
TSH > ULN WITH TSH ≤ ULN AT BASELINE	0	0	0	1
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0	0	0	0
TSH < LLN	0	0	0	0
TSH <LLN WITH TSH ≥ LLN AT BASELINE	0	0	0	0
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	0	0	0

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	11	188
Units: Participants				
TSH > ULN	1	4	5	72
TSH > ULN WITH TSH ≤ ULN AT BASELINE	0	4	2	42
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0	0	0	37
TSH < LLN	1	4	2	38
TSH <LLN WITH TSH ≥ LLN AT BASELINE	0	3	2	26
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	1	1	25

End point values	Part E: BMS-986156 480mg + Nivo 480mg			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Participants				
TSH > ULN	19			
TSH > ULN WITH TSH ≤ ULN AT BASELINE	11			
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	9			
TSH < LLN	10			
TSH <LLN WITH TSH ≥ LLN AT BASELINE	8			
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	5			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with laboratory abnormalities in specific liver tests

End point title	Number of Participants with laboratory abnormalities in specific liver tests[3]

End point description:

Number of Participants with laboratory abnormalities in specific liver tests.

ALT
AST
ALP
T Bili = Total bilirubin

End point type	Primary

End point timeframe:

Approximately up to 29 months

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 statistical analysis done for this endpoint

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Participants				
ALT OR AST > 3*ULN	0	1	0	0
ALT OR AST> 5*ULN	0	0	0	0
ALT OR AST> 10*ULN	0	0	0	0
ALT OR AST > 20*ULN	0	0	0	0
TOTAL BILIRUBIN > 2*ULN	0	1	0	0
ALP > 1.5*ULN	1	2	1	2
ALT/AST ELEV>3*ULN; T BILI>2*ULN IN 1 DAY	0	1	1	0
ALT/AST ELEV>3*ULN;T BILI >2*ULN IN 30 DAYS	0	1	1	0

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3
Units: Participants				
ALT OR AST > 3*ULN	1	0	0	0
ALT OR AST> 5*ULN	1	0	1	0
ALT OR AST> 10*ULN	0	0	0	0
ALT OR AST > 20*ULN	0	0	0	0
TOTAL BILIRUBIN > 2*ULN	0	0	0	1
ALP > 1.5*ULN	2	1	1	2
ALT/AST ELEV>3*ULN; T BILI>2*ULN IN 1 DAY	0	0	0	0
ALT/AST ELEV>3*ULN;T BILI >2*ULN IN 30 DAYS	0	0	0	0

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	13	11	188
Units: Participants				
ALT OR AST > 3*ULN	1	3	2	25
ALT OR AST> 5*ULN	1	2	2	14
ALT OR AST> 10*ULN	0	2	0	6
ALT OR AST > 20*ULN	0	1	0	1
TOTAL BILIRUBIN > 2*ULN	0	1	0	5
ALP > 1.5*ULN	2	7	3	70
ALT/AST ELEV>3*ULN; T BILI>2*ULN IN 1 DAY	0	0	1	6
ALT/AST ELEV>3*ULN;T BILI >2*ULN IN 30 DAYS	0	0	1	7

End point values	Part E: BMS-986156 480mg + Nivo 480mg			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Participants				
ALT OR AST > 3*ULN	3			
ALT OR AST> 5*ULN	1			
ALT OR AST> 10*ULN	0			
ALT OR AST > 20*ULN	0			
TOTAL BILIRUBIN > 2*ULN	1			
ALP > 1.5*ULN	11			
ALT/AST ELEV>3*ULN; T BILI>2*ULN IN 1 DAY	1			
ALT/AST ELEV>3*ULN;T BILI >2*ULN IN 30 DAYS	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response

End point title	Best Overall Response

End point description:

Defined as the best response designation over the study as a whole, recorded between the dates of first dose until the last tumor assessment prior to subsequent therapy.

End point type	Secondary

End point timeframe:

Approximately 50 Months

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	0	0	0
Stable Disease	2	1	2	1
Progressive Disease	1	3	2	4
Not Evaluable	1	2	0	1
Not Available	0	0	0	0

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	0	0	1
Stable Disease	4	1	0	2
Progressive Disease	4	2	2	0
Not Evaluable	1	0	0	0
Not Available	0	0	0	0

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	11	188
Units: Participants				
Complete Response	0	0	0	4
Partial Response	1	3	1	17
Stable Disease	2	6	6	59
Progressive Disease	4	4	4	91
Not Evaluable	2	1	0	16
Not Available	0	0	0	1

End point values	Part E: BMS-986156 480mg + Nivo 480mg			

Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Participants				
Complete Response	2			
Partial Response	1			
Stable Disease	12			
Progressive Disease	15			
Not Evaluable	3			
Not Available	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate

End point title	Overall Response Rate

End point description:

Defined as the percentage of all treated participants whose BOR is either a complete response(CR) or partial response(PR).

End point type	Secondary

End point timeframe:

Approximately 50 Months

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 60.2)	0 (0.0 to 45.9)	0 (0.0 to 60.2)	0 (0.0 to 45.9)

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 33.6)	0 (0.0 to 70.8)	0 (0.0 to 84.2)	0 (0.0 to 70.8)

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	11	188

Units: Percentage of participants				
number (confidence interval 95%)	11.1 (0.3 to 48.2)	21.4 (4.7 to 50.8)	9.1 (0.2 to 41.3)	11.2 (7.0 to 16.6)

End point values	Part E: BMS-986156 480mg + Nivo 480mg			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Percentage of participants				
number (confidence interval 95%)	9.1 (1.9 to 24.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

The time from the first dosing date to the date of first objectively documented disease progression or death due to any cause, whichever occurs first.

Here "-9999 and 9999" equals NA

End point type	Secondary

End point timeframe:

Approximately 50 Months

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Months				
median (confidence interval 95%)	3.48 (1.64 to 9999)	1.74 (1.45 to 9999)	2.66 (1.64 to 9999)	1.64 (1.58 to 9999)

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3
Units: Months				
median (confidence interval 95%)	1.84 (1.64 to 3.48)	1.64 (1.64 to 9999)	1.71 (-9999 to 9999)	1.81 (1.64 to 9999)

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	11	188
Units: Months				
median (confidence interval 95%)	1.64 (0.89 to 22.47)	3.71 (1.64 to 8.97)	3.52 (1.61 to 9999)	1.91 (1.81 to 3.25)

End point values	Part E: BMS-986156 480mg + Nivo 480mg			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Months				
median (confidence interval 95%)	2.92 (1.77 to 3.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response

End point description:

All treated participants with a BOR of CR or PR, is defined as the time between the date of first response and the date of disease progression or death, whichever occurs first.

Here "0.9999 and 21.9999" indicate values not calculable.

End point type	Secondary

End point timeframe:

Approximately 50 Months

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[4]	0[5]	0[6]	0[7]
Units: Months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[4] - No subjects analyzed

[5] - No subjects analyzed

[6] - No subjects analyzed

[7] - No subjects analyzed

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[8]	0[9]	0[10]	0[11]
Units: Months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[8] - No subjects analyzed

[9] - No subjects analyzed

[10] - No subjects analyzed

[11] - No subjects analyzed

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	1[12]	20
Units: Months				
median (full range (min-max))	20.70 (20.7 to 20.7)	30.10 (7.4 to 31.3)	31.0 (31.0 to 31.0)	0.9999 (0.0 to 31.8)

Notes:

[12] - Median value not calculable

End point values	Part E: BMS-986156 480mg + Nivo 480mg			
Subject group type	Reporting group			
Number of subjects analysed	3[13]			
Units: Months				
median (full range (min-max))	21.9999 (21.0 to 22.4)			

Notes:

[13] - Median value not calculable

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-Drug Antibody Response

End point title	Number of Participants with Anti-Drug Antibody Response

End point description:

Number of participants with a positive Anti-Drug Antibody to BMS-986156 or nivolumab

Here "9999" means not available. subjects did not receive nivolumab

End point type	Secondary

End point timeframe:

At Cycle 3 Day 1 (Approximately 30 days)

End point values	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg	Part A: BMS-986156 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	4	6
Units: Participants				
BMS-986156	1	0	0	0
Nivolumab	9999	9999	9999	9999

End point values	Part A: BMS-986156 800mg	Part C: BMS-986156 240mg	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	2	3
Units: Participants				
BMS-986156	0	0	0	1
Nivolumab	9999	9999	9999	0

End point values	Part B: BMS-986156 100mg + Nivo 240mg	Part B: BMS-986156 240mg + Nivo 240mg	Part B: BMS-986156 800mg + Nivo 240mg	Part D: BMS-986156 240mg + Nivo 240mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	14	11	188
Units: Participants				
BMS-986156	0	0	0	5
Nivolumab	0	4	1	32

End point values	Part E: BMS-986156 480mg + Nivo 480mg			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Participants				
BMS-986156	0			
Nivolumab	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs/SAEs are collected from the first dose date until the last dose date + 100 days. (Approximately up to 29 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Part A: BMS-986156 10mg
Reporting group description:	
BMS986156 10mg Q2W	
Reporting group title	Part A: BMS-986156 30mg
Reporting group description:	
BMS986156 30mg Q2W	
Reporting group title	Part A: BMS-986156 100mg
Reporting group description:	
BMS-986156 100mg Q2W	
Reporting group title	Part A: BMS-986156 240mg
Reporting group description:	
BMS-986156 240mg Q2W	
Reporting group title	Part C: BMS-986156 240mg
Reporting group description:	
BMS-986156 240mg Q2W	
Reporting group title	Part A: BMS-986156 800mg
Reporting group description:	
BMS-986156 800mg Q2W	
Reporting group title	Part C: BMS-986156 800mg
Reporting group description:	
BMS-986156 240mg Q2W	
Reporting group title	Part B: BMS-986156 30mg +Nivo 240mg
Reporting group description:	
BMS-986156 30mg Q2W +Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 100mg +Nivo 240mg
Reporting group description:	
BMS-986156 100mg Q2W +Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 240mg +Nivo 240mg
Reporting group description:	
BMS-986156 240mg Q2W +Nivo 240mg Q2W	
Reporting group title	Part B: BMS-986156 800mg +Nivo 240mg
Reporting group description:	
BMS-986156 800mg Q2W +Nivo 240mg Q2W	
Reporting group title	Part D: BMS-986156 240mg +Nivo 240mg
Reporting group description:	
BMS-986156 240mg Q2W +Nivo 240mg Q2W	
Reporting group title	Part E: BMS-986156 480mg Q4W +Nivo 480mg Q4W
Reporting group description:	
BMS-986156 480mg Q4W +Nivo 480mg Q4W	

Serious adverse events	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	3 / 6 (50.00%)	1 / 4 (25.00%)
number of deaths (all causes)	4	5	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	3 / 4 (75.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 pancreas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 occlusive disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Femur fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site extravasation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis noninfective			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
Ectopic antidiuretic hormone secretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 A: BMS-986156 240mg	Part C: BMS-986156 240mg	Part A: BMS-986156 800mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	2 / 3 (66.67%)	4 / 9 (44.44%)
number of deaths (all causes)	5	2	6
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	3 / 9 (33.33%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 pancreas			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 occlusive disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Disease progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Uterine haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatic enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Femur fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site extravasation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis noninfective			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	1 / 9 (11.11%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	1 / 9 (11.11%)
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			
Bile duct obstruction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Skin lesion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Ectopic antidiuretic hormone secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 C: BMS-986156 800mg	Part B: BMS-986156 30mg +Nivo 240mg	Part B: BMS-986156 100mg +Nivo 240mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 3 (66.67%)	5 / 9 (55.56%)
number of deaths (all causes)	2	3	6
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	2 / 2 (100.00%)	2 / 3 (66.67%)	3 / 9 (33.33%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 3
Metastases to central nervous system			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 pancreas			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 occlusive disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			

Disease progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Perineal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical condition abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Femur fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site extravasation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stoma site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis noninfective			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			

Ataxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Skin lesion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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			
Ectopic antidiuretic hormone secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (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
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
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 B: BMS-986156 240mg +Nivo 240mg	Part B: BMS-986156 800mg +Nivo 240mg	Part D: BMS-986156 240mg +Nivo 240mg
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 14 (71.43%)	6 / 11 (54.55%)	121 / 188 (64.36%)
number of deaths (all causes)	11	8	141
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	4 / 14 (28.57%)	2 / 11 (18.18%)	72 / 188 (38.30%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 74
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 63
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 pancreas			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial occlusive disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	0 / 188 (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
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (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 creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (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
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site extravasation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Endocarditis noninfective			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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			
Ataxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Febrile neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (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
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
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			

Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Ectopic antidiuretic hormone secretion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Soft tissue infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
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 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part E: BMS-986156		

	480mg Q4W +Nivo 480mg Q4W		
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 33 (66.67%)		
number of deaths (all causes)	27		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant ascites			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			
subjects affected / exposed	13 / 33 (39.39%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 12		
Metastases to central nervous system			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to pancreas			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm malignant			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour haemorrhage			

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Arterial occlusive disease				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhage				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Disease progression				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Inflammation			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Performance status decreased			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine haemorrhage			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional state				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General physical condition abnormal				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal fracture			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stoma obstruction			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stoma site extravasation			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stoma site pain			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Atrial flutter				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis noninfective				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Ataxia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial paralysis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				

subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thalamus haemorrhage				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bone marrow failure				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal distension				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	3 / 33 (9.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal perforation				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct obstruction				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin lesion				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephritis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureteric haemorrhage				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract obstruction				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urogenital fistula				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Ectopic antidiuretic hormone secretion				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid mass				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pain in extremity				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abdominal infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary tract infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extradural abscess				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Kidney infection				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				

subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				

subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part A: BMS-986156 10mg	Part A: BMS-986156 30mg	Part A: BMS-986156 100mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	5 / 6 (83.33%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	3	2	1
Feeling abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dry throat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nasal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Headache			

subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	3 / 6 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal pain upper			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 4 (50.00%)	2 / 6 (33.33%)	1 / 4 (25.00%)
occurrences (all)	2	3	1
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 6 (50.00%)	1 / 4 (25.00%)
occurrences (all)	3	3	1
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative generalised			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nail ridging			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Sensitive skin			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haemorrhage urinary tract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Kidney congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Herpes simplex			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Dehydration			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Gout			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: BMS-986156 240mg	Part C: BMS-986156 240mg	Part A: BMS-986156 800mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Tumour pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Early satiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)	2 / 3 (66.67%)	3 / 9 (33.33%)
occurrences (all)	2	2	3
Feeling abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	2
Pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Pyrexia			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	3 / 9 (33.33%)
occurrences (all)	3	0	3
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dysmenorrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Scrotal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dry throat			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	1	1	2
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Mood altered			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Blood potassium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Post procedural haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	3	0	2
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Increased tendency to bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	3 / 9 (33.33%)
occurrences (all)	2	0	3
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	2	3	2

Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	4 / 9 (44.44%)
occurrences (all)	0	2	5
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	4	1	2

Stomatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	3 / 9 (33.33%)
occurrences (all)	0	2	4
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail ridging			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sensitive skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhage urinary tract			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Kidney congestion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Bone pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Flank pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			

Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	1	2	2
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gout			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part C: BMS-986156 800mg	Part B: BMS-986156 30mg +Nivo 240mg	Part B: BMS-986156 100mg +Nivo 240mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	8 / 9 (88.89%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Tumour pain			

subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Feeling abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	3 / 9 (33.33%)
occurrences (all)	0	3	3
Reproductive system and breast			

disorders			
Breast tenderness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dysmenorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Dry throat			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nasal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Mood altered			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lipase increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	8
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Post procedural haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Increased tendency to bruise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	3
Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Anal incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	4
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Eructation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gingival bleeding			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	5
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
Hepatic pain			

subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Sensitive skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Kidney congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Nephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Furuncle			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	7
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Steroid diabetes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B: BMS-986156 240mg +Nivo 240mg	Part B: BMS-986156 800mg +Nivo 240mg	Part D: BMS-986156 240mg +Nivo 240mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	11 / 11 (100.00%)	185 / 188 (98.40%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	11 / 188 (5.85%)
occurrences (all)	0	1	11
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	11 / 188 (5.85%)
occurrences (all)	0	0	12
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	1	0	2
Hypertension			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	6 / 188 (3.19%)
occurrences (all)	1	1	7
Hypotension			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences (all)	0	0	5
Orthostatic hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Vascular compression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	27 / 188 (14.36%)
occurrences (all)	0	0	29
Catheter site erythema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	0	0	8
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	11 / 188 (5.85%)
occurrences (all)	0	0	11
Chills			
subjects affected / exposed	4 / 14 (28.57%)	2 / 11 (18.18%)	15 / 188 (7.98%)
occurrences (all)	4	2	16
Early satiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 14 (35.71%)	7 / 11 (63.64%)	57 / 188 (30.32%)
occurrences (all)	5	7	64
Feeling abnormal			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Feeling hot			

subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences (all)	0	2	1
Gait disturbance			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences (all)	0	1	2
Influenza like illness			
subjects affected / exposed	2 / 14 (14.29%)	1 / 11 (9.09%)	11 / 188 (5.85%)
occurrences (all)	3	1	13
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	2 / 11 (18.18%)	5 / 188 (2.66%)
occurrences (all)	0	3	5
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	4 / 188 (2.13%)
occurrences (all)	0	1	4
Oedema peripheral			
subjects affected / exposed	1 / 14 (7.14%)	3 / 11 (27.27%)	25 / 188 (13.30%)
occurrences (all)	1	3	25
Pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	17 / 188 (9.04%)
occurrences (all)	0	1	17
Pyrexia			
subjects affected / exposed	5 / 14 (35.71%)	5 / 11 (45.45%)	34 / 188 (18.09%)
occurrences (all)	6	6	41
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Testicular pain			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	1
Vaginal discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	0	0	9
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 14 (35.71%)	1 / 11 (9.09%)	31 / 188 (16.49%)
occurrences (all)	5	1	38
Dry throat			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	2	0	0
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	0	0	7
Dyspnoea			
subjects affected / exposed	1 / 14 (7.14%)	2 / 11 (18.18%)	29 / 188 (15.43%)
occurrences (all)	1	2	31
Dyspnoea exertional			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences (all)	1	0	5
Epistaxis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences (all)	1	0	5
Nasal congestion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	1	0	4
Nasal discomfort			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	1	0	7
Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	0	0	11
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	0	0	7
Rhinorrhoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	1	0	3
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 14 (21.43%)	1 / 11 (9.09%)	7 / 188 (3.72%)
occurrences (all)	4	1	7
Confusional state			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	1
Depressed mood			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	1	0	6
Insomnia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 11 (0.00%)	12 / 188 (6.38%)
occurrences (all)	7	0	12
Mood altered			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 14 (14.29%)	1 / 11 (9.09%)	8 / 188 (4.26%)
occurrences (all)	4	1	10
Amylase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	0	0	7
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	11 / 188 (5.85%)
occurrences (all)	2	2	14
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	3	0	3
Blood bilirubin increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	4 / 188 (2.13%)
occurrences (all)	1	1	6
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	4 / 188 (2.13%)
occurrences (all)	0	2	4
Blood creatinine increased			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	11 / 188 (5.85%)
occurrences (all)	2	0	17
Blood potassium decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	0	0	9
Neutrophil count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	2	0	1
Platelet count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	2 / 188 (1.06%)
occurrences (all)	0	1	2
Weight decreased			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	9 / 188 (4.79%)
occurrences (all)	1	0	9
Weight increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	1	0	2
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	1
Infusion related reaction			
subjects affected / exposed	1 / 14 (7.14%)	2 / 11 (18.18%)	20 / 188 (10.64%)
occurrences (all)	1	3	24
Post procedural haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	1	0	4
Rib fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Stoma site pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	10 / 188 (5.32%)
occurrences (all)	3	0	12
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Headache			

subjects affected / exposed	5 / 14 (35.71%)	3 / 11 (27.27%)	22 / 188 (11.70%)
occurrences (all)	10	6	33
Lethargy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Myoclonus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	1
Neuropathy peripheral			
subjects affected / exposed	2 / 14 (14.29%)	1 / 11 (9.09%)	6 / 188 (3.19%)
occurrences (all)	2	1	7
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	4 / 188 (2.13%)
occurrences (all)	0	1	4
Peripheral sensory neuropathy			
subjects affected / exposed	4 / 14 (28.57%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	5	0	2
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 14 (21.43%)	2 / 11 (18.18%)	30 / 188 (15.96%)
occurrences (all)	3	2	35
Increased tendency to bruise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences (all)	0	1	1

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	2
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	2 / 188 (1.06%)
occurrences (all)	1	1	2
Eye discharge			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Periorbital swelling			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	1	0	3
Visual impairment			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	0	0	2
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	10 / 188 (5.32%)
occurrences (all)	0	0	12
Abdominal pain			
subjects affected / exposed	3 / 14 (21.43%)	2 / 11 (18.18%)	22 / 188 (11.70%)
occurrences (all)	3	2	25
Abdominal pain lower			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	5 / 188 (2.66%)
occurrences (all)	0	1	6
Abdominal pain upper			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	8 / 188 (4.26%)
occurrences (all)	0	0	11
Anal incontinence			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	10 / 188 (5.32%)
occurrences (all)	1	0	14
Colitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	2 / 11 (18.18%)	28 / 188 (14.89%)
occurrences (all)	1	2	29
Diarrhoea			
subjects affected / exposed	4 / 14 (28.57%)	3 / 11 (27.27%)	35 / 188 (18.62%)
occurrences (all)	8	4	51
Dry mouth			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	3	0	4
Dyspepsia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	1	0	4
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	7 / 188 (3.72%)
occurrences (all)	0	1	7
Eructation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	0	0	4
Gingival bleeding			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	5	0	0
Intestinal obstruction			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Lip dry			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	5 / 14 (35.71%)	5 / 11 (45.45%)	44 / 188 (23.40%)
occurrences (all)	9	5	59
Stomatitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	2	0	1
Toothache			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	2 / 188 (1.06%)
occurrences (all)	0	1	2
Vomiting			
subjects affected / exposed	8 / 14 (57.14%)	2 / 11 (18.18%)	28 / 188 (14.89%)
occurrences (all)	11	3	53
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	0	0	4
Dermatitis acneiform			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences (all)	1	1	1
Dermatitis exfoliative generalised			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	1	0	8
Eczema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	6 / 188 (3.19%)
occurrences (all)	0	1	7
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	0	0	2
Nail ridging			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	2	0	2
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 14 (0.00%)	2 / 11 (18.18%)	1 / 188 (0.53%)
occurrences (all)	0	2	1
Pruritus			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	21 / 188 (11.17%)
occurrences (all)	2	0	27
Rash			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	15 / 188 (7.98%)
occurrences (all)	2	0	15
Rash macular			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	2 / 188 (1.06%)
occurrences (all)	0	2	2
Rash maculo-papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	0	0	6

Sensitive skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	0	0	6
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences (all)	0	0	6
Haemorrhage urinary tract			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Kidney congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	0	0	3
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	10 / 188 (5.32%)
occurrences (all)	0	0	12
Hypothyroidism			

subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	11 / 188 (5.85%)
occurrences (all)	0	0	15
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 14 (21.43%)	3 / 11 (27.27%)	20 / 188 (10.64%)
occurrences (all)	3	3	22
Back pain			
subjects affected / exposed	2 / 14 (14.29%)	5 / 11 (45.45%)	25 / 188 (13.30%)
occurrences (all)	3	5	26
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	0	0	3
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	8 / 188 (4.26%)
occurrences (all)	0	1	8
Groin pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences (all)	0	0	5
Muscle spasms			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	5 / 188 (2.66%)
occurrences (all)	1	0	5
Muscular weakness			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	9 / 188 (4.79%)
occurrences (all)	1	1	9
Musculoskeletal chest pain			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	3	0	2
Musculoskeletal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	4 / 188 (2.13%)
occurrences (all)	0	1	4
Myalgia			

subjects affected / exposed	2 / 14 (14.29%)	4 / 11 (36.36%)	11 / 188 (5.85%)
occurrences (all)	2	4	11
Neck pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 11 (9.09%)	5 / 188 (2.66%)
occurrences (all)	1	1	5
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	15 / 188 (7.98%)
occurrences (all)	1	0	16
Pain in jaw			
subjects affected / exposed	2 / 14 (14.29%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	2	0	2
Synovial cyst			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	2
Ear infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Epididymitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	0 / 188 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0

Herpes simplex			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	1	0	2
Otitis media			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	0	0	2
Pharyngitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	1	0	2
Pneumonia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	3 / 188 (1.60%)
occurrences (all)	1	0	3
Respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	1	0	2
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	2 / 188 (1.06%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	0	0	4
Tooth infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	1	0	2

Upper respiratory tract infection			
subjects affected / exposed	2 / 14 (14.29%)	2 / 11 (18.18%)	8 / 188 (4.26%)
occurrences (all)	2	2	9
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	11 / 188 (5.85%)
occurrences (all)	1	0	15
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 14 (35.71%)	4 / 11 (36.36%)	34 / 188 (18.09%)
occurrences (all)	9	4	34
Dehydration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	4 / 188 (2.13%)
occurrences (all)	1	0	5
Gout			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	1 / 188 (0.53%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	1	0	10
Hypoalbuminaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 11 (9.09%)	1 / 188 (0.53%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	7 / 188 (3.72%)
occurrences (all)	0	0	7
Hypomagnesaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	9 / 188 (4.79%)
occurrences (all)	2	0	10
Hyponatraemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	1	0	7
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	6 / 188 (3.19%)
occurrences (all)	0	0	8
Steroid diabetes			

subjects affected / exposed	1 / 14 (7.14%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 11 (0.00%)	0 / 188 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part E: BMS-986156 480mg Q4W +Nivo 480mg Q4W		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 33 (93.94%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Tumour pain			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Vascular disorders			
Embolism			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Hot flush			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Hypertension			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Orthostatic hypotension			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Vascular compression			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
General disorders and administration			

site conditions				
Asthenia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Catheter site erythema				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Chest discomfort				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Chest pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Chills				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	3			
Early satiety				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	15 / 33 (45.45%)			
occurrences (all)	16			
Feeling abnormal				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Feeling hot				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Gait disturbance				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Malaise				

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	6 / 33 (18.18%)		
occurrences (all)	9		
Pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Reproductive system and breast disorders			
Breast tenderness			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Scrotal oedema			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Testicular pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Vaginal discharge			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Vaginal haemorrhage			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			

Cough				
subjects affected / exposed	7 / 33 (21.21%)			
occurrences (all)	7			
Dry throat				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Dysphonia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	6 / 33 (18.18%)			
occurrences (all)	6			
Dyspnoea exertional				
subjects affected / exposed	3 / 33 (9.09%)			
occurrences (all)	3			
Epistaxis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Nasal congestion				
subjects affected / exposed	3 / 33 (9.09%)			
occurrences (all)	3			
Nasal discomfort				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	3 / 33 (9.09%)			
occurrences (all)	3			
Pleural effusion				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Pneumonitis				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Productive cough				
subjects affected / exposed	4 / 33 (12.12%)			
occurrences (all)	4			

Rhinorrhoea			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Confusional state			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Depressed mood			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Mood altered			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Amylase increased			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Blood potassium decreased			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Weight increased			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Fall			

subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	2		
Infusion related reaction			
subjects affected / exposed	6 / 33 (18.18%)		
occurrences (all)	6		
Post procedural haemorrhage			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Procedural pain			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Rib fracture			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Stoma site pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	4		
Dysgeusia			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Lethargy			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Myoclonus			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		

Neuralgia subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Paraesthesia subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Somnolence subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 5		
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Eye disorders Dry eye subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2		
Eye discharge subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Eye pain			

subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Periorbital swelling			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Visual impairment			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	9 / 33 (27.27%)		
occurrences (all)	9		
Abdominal pain lower			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Anal incontinence			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Colitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		

Constipation				
subjects affected / exposed	7 / 33 (21.21%)			
occurrences (all)	7			
Diarrhoea				
subjects affected / exposed	6 / 33 (18.18%)			
occurrences (all)	7			
Dry mouth				
subjects affected / exposed	6 / 33 (18.18%)			
occurrences (all)	6			
Dyspepsia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Eructation				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Gingival bleeding				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Intestinal obstruction				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Lip dry				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Mesenteric vein thrombosis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			

Nausea subjects affected / exposed occurrences (all)	12 / 33 (36.36%) 16		
Stomatitis subjects affected / exposed occurrences (all)	4 / 33 (12.12%) 5		
Toothache subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Vomiting subjects affected / exposed occurrences (all)	8 / 33 (24.24%) 11		
Hepatobiliary disorders Hepatic pain subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Dermatitis exfoliative generalised subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Eczema subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Erythema subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Hyperhidrosis			

subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Nail ridging			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Rash macular			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Sensitive skin			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Dysuria			

subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Haemorrhage urinary tract			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Kidney congestion			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Nephritis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 33 (15.15%)		
occurrences (all)	5		
Back pain			
subjects affected / exposed	4 / 33 (12.12%)		
occurrences (all)	4		
Bone pain			

subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Flank pain				
subjects affected / exposed	5 / 33 (15.15%)			
occurrences (all)	5			
Groin pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Muscle spasms				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Muscular weakness				
subjects affected / exposed	3 / 33 (9.09%)			
occurrences (all)	3			
Musculoskeletal chest pain				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Musculoskeletal discomfort				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Musculoskeletal pain				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Myalgia				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	2			
Neck pain				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Pain in extremity				
subjects affected / exposed	4 / 33 (12.12%)			
occurrences (all)	4			
Pain in jaw				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Synovial cyst				

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Epididymitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Furuncle			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		

Otitis externa			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Respiratory tract infection			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Tooth infection			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	4 / 33 (12.12%)		
occurrences (all)	5		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 33 (15.15%)		
occurrences (all)	5		
Dehydration			

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Hypoalbuminaemia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	3		
Hypomagnesaemia			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Hyponatraemia			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		
Hypophosphataemia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Steroid diabetes			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	2 / 33 (6.06%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 July 2016	Identification of additional tumor types to be explored during Part D of the study design Revision of tumor types to be explored Starting dose of BMS-936558 in combination with Nivolumab clarified Dose duration of Nivolumab for Part B & D included
16 September 2016	The purpose of this amendment is to address HA feedback and to make clarifying changes. Provides clarification for further dose options for BMS-986156 Updates sections of the protocol with the latest safety data for BMS-986156 monotherapy and BMS-986156 in combination with nivolumab Clarifies effective methods of contraception Restrict the population of NSCLC subjects to those with progressive or recurrent disease after prior platinum doublet-based chemotherapy Modify inclusion criteria for subjects with bladder cancer and ovarian cancer Added additional PD assessments
31 January 2017	The changes in this amendment include addition of dose expansion cohorts using every 4 week dosing in cervical cancer and in a multitumor type cohort including tumors allowed in dose escalation in combination of BMS 986156 with nivolumab, Clarifies inclusion criteria for the SCCHN, HCC and ovarian cancer cohorts, Updates clinical safety information, Updates the statistical section Updates the contraceptive language Added additional PD assessments
22 November 2017	The changes in this amendment include extending treatment for up to total of 2 years, or up to 7 additional cycles.
08 March 2019	This revision reflects to following changes: Incorporates Administrative Letter 04 Halts all PK, PD, immunogenicity, and biomarker sampling and analyses Removes the Response and Survival Follow-up Phases Removes Retreatment option during Survival follow-up Includes minor typographical changes throughout

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported