



Clinical trial results:

A Phase 1b/2 Study of BMS-813160 in Combination with Chemotherapy or Nivolumab in Patients with Advanced Solid Tumors

Summary

EudraCT number	2017-001725-40
Trial protocol	DE ES BE IT
Global end of trial date	14 June 2023

Results information

Result version number	v1 (current)
This version publication date	30 June 2024
First version publication date	30 June 2024

Trial information

Trial identification

Sponsor protocol code	CV202-103
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, 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	14 June 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 June 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of BMS-813160 in combination with either FOLFIRI (Arm A), Gem + nab-paclitaxel (Arm B), or nivolumab (Arm C) in participants with advanced CRC or pancreatic cancer and to assess the pharmacodynamic effects of BMS-813160 in tumor samples

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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 August 2017
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	Canada: 27
Country: Number of subjects enrolled	United States: 252
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Spain: 24
Country: Number of subjects enrolled	Australia: 2
Worldwide total number of subjects	324
EEA total number of subjects	43

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)	201
From 65 to 84 years	121
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants in Cohort 1c were given the option to cross over to Cohort 8 if it's in their best interest by their treating physician. Participants will have to meet all eligibility criteria to reenter the study, undergo baseline assessment and need a 28-day washout period prior to first dose of study treatment in the new arm.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI
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Arm description:

First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer

Arm type	Experimental
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

5-fluorouracil injection

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan injection

Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Leucovorin injection

Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

BMS-813160 300 mg twice a day

Arm title	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI
Arm description: First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 600 mg once a day	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Leucovorin injection	
Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Irinotecan injection	
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: 5-fluorouracil injection	
Arm title	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB
Arm description: First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg twice a day	
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nab-paclitaxel 100 mg injection	

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Gemcitabine 1000 mg injection	
Arm title	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Arm description: First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE)	
Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 600 mg once a day	
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nab-paclitaxel 100 mg injection	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Gemcitabine 1000 mg injection	
Arm title	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO
Arm description: Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg twice a day	

Arm title	Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO
Arm description: Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Tablet
Routes of administration	Oral use, Oral use
Dosage and administration details: BMS-813160 600 mg once a day	
Arm title	Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO
Arm description: Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg once a day	
Arm title	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Arm description: Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	

Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 150 mg once a day	
Arm title	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO
Arm description: Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg twice a day	
Arm title	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO
Arm description: Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 600 mg once a day	
Arm title	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI
Arm description: Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer	
Arm type	Experimental

Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg twice a day	
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: 5-fluorouracil injection	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Leucovorin injection	
Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Irinotecan injection	
Arm title	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Arm description: Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 150 mg once a day	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Leucovorin injection	
Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:	
Irinotecan injection	
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
5-fluorouracil injection	
Arm title	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI
Arm description:	
Second-line treatment FOLFIRI in participants with colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	5-fluorouracil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
5-fluorouracil injection	
Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
Irinotecan injection	
Investigational medicinal product name	Leucovorin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
Leucovorin injection	
Arm title	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB
Arm description:	
First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
BMS-813160 300 mg twice a day	
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:	
Nab-paclitaxel 100 mg injection	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
Gemcitabine 1000 mg injection	
Arm title	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO
Arm description:	
First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
BMS-813160 300 mg twice a day	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
Nivolumab 10 mg/mL	
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
Nab-paclitaxel 100 mg injection	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
Gemcitabine 1000 mg injection	
Arm title	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Arm description:	
First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details: Nab-paclitaxel 100 mg injection	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Gemcitabine 1000 mg injection	
Arm title	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO
Arm description: Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg twice a day	
Arm title	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO
Arm description: Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 10 mg/mL	
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: BMS-813160 300 mg twice a day	

Number of subjects in period 1	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB
Started	10	8	10
Cross-over	0	0	0
Completed	0	0	0
Not completed	10	8	10
Adverse event, serious fatal	6	6	8
Consent withdrawn by subject	-	-	2
Other Reasons	2	2	-
Lost to follow-up	2	-	-

Number of subjects in period 1	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO
Started	11	8	7
Cross-over	0	0	0
Completed	0	0	0
Not completed	11	8	7
Adverse event, serious fatal	8	6	6
Consent withdrawn by subject	1	1	-
Other Reasons	1	-	-
Lost to follow-up	1	1	1

Number of subjects in period 1	Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO
Started	7	11	1
Cross-over	0	0	0
Completed	0	0	0
Not completed	7	11	1
Adverse event, serious fatal	6	7	1
Consent withdrawn by subject	1	-	-
Other Reasons	-	2	-
Lost to follow-up	-	2	-

Number of subjects in period 1	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Started	2	32	32
Cross-over	0	0	0
Completed	0	0	0
Not completed	2	32	32
Adverse event, serious fatal	2	26	28

Consent withdrawn by subject	-	-	2
Other Reasons	-	4	2
Lost to follow-up	-	2	-

Number of subjects in period 1	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO
Started	26	35	35
Cross-over	9	0	0
Completed	0	0	0
Not completed	26	35	35
Adverse event, serious fatal	17	33	34
Consent withdrawn by subject	3	-	1
Other Reasons	4	-	-
Lost to follow-up	2	2	-

Number of subjects in period 1	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO
Started	32	24	33
Cross-over	0	0	0
Completed	0	0	0
Not completed	32	24	33
Adverse event, serious fatal	26	20	25
Consent withdrawn by subject	5	2	2
Other Reasons	1	-	4
Lost to follow-up	-	2	2

Baseline characteristics

Reporting groups

Reporting group title	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI
Reporting group description: First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer	
Reporting group title	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI
Reporting group description: First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer	
Reporting group title	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB
Reporting group description: First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer	
Reporting group title	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Reporting group description: First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE)	
Reporting group title	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO
Reporting group description: Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer	
Reporting group title	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO
Reporting group description: Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer	
Reporting group title	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI
Reporting group description: Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer	
Reporting group title	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Reporting group description: Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer	
Reporting group title	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI
Reporting group description: Second-line treatment FOLFIRI in participants with colorectal cancer	
Reporting group title	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer

Reporting group title	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO
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Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer

Reporting group title	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
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Reporting group description:

First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer

Reporting group title	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO
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Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

Reporting group title	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Reporting group values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB
Number of subjects	10	8	10
Age categorical Units: Subjects			
Adults (18-64 years)	4	5	5
From 65-84 years	6	3	5
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	65.6	53.3	64.1
full range (min-max)	54 to 83	28 to 66	54 to 80
Sex: Female, Male Units: Participants			
Female	3	2	6
Male	7	6	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	3	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	8	4	10
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	8	5	8
Unknown or Not Reported	2	3	1

Reporting group values	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO
Number of subjects	11	8	7
Age categorical Units: Subjects			
Adults (18-64 years)	7	6	6
From 65-84 years	4	2	1
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	62.7	59.5	61.7
full range (min-max)	51 to 80	48 to 76	52 to 66
Sex: Female, Male Units: Participants			
Female	6	2	3
Male	5	6	4
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	1
White	11	8	5
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	9	8	7
Unknown or Not Reported	1	0	0

Reporting group values	Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO
Number of subjects	7	11	1
Age categorical Units: Subjects			
Adults (18-64 years)	7	8	1
From 65-84 years	0	3	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	45.1	60.5	61.0
full range (min-max)	33 to 57	42 to 77	61 to 61
Sex: Female, Male Units: Participants			
Female	3	3	1
Male	4	8	0

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	2	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	7	7	1
More than one race	0	0	0
Unknown or Not Reported	0	2	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	3	0
Not Hispanic or Latino	6	7	0
Unknown or Not Reported	1	1	1

Reporting group values	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Number of subjects	2	32	32
Age categorical			
Units: Subjects			
Adults (18-64 years)	2	25	21
From 65-84 years	0	7	11
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	50.0	55.0	58.9
full range (min-max)	49 to 51	29 to 76	30 to 83
Sex: Female, Male			
Units: Participants			
Female	0	13	11
Male	2	19	21
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	2	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	3
White	2	28	26
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	7	2
Not Hispanic or Latino	2	21	26
Unknown or Not Reported	0	4	4

Reporting group values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO
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Number of subjects	26	35	35
Age categorical			
Units: Subjects			
Adults (18-64 years)	20	13	16
From 65-84 years	6	22	17
85 years and over	0	0	2
Age Continuous			
Units: Years			
arithmetic mean	57.9	65.9	65.3
full range (min-max)	37 to 77	46 to 76	43 to 85
Sex: Female, Male			
Units: Participants			
Female	9	15	15
Male	17	20	20
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	2	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	0
White	22	32	34
More than one race	0	0	0
Unknown or Not Reported	1	1	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	2	1
Not Hispanic or Latino	17	28	30
Unknown or Not Reported	7	5	4

Reporting group values	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO
Number of subjects	32	24	33
Age categorical			
Units: Subjects			
Adults (18-64 years)	15	11	29
From 65-84 years	17	13	4
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	65.5	63.9	55.0
full range (min-max)	49 to 84	34 to 77	39 to 69
Sex: Female, Male			
Units: Participants			
Female	15	8	18
Male	17	16	15
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	1

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	3
White	27	22	28
More than one race	0	0	0
Unknown or Not Reported	2	1	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	4	0	4
Not Hispanic or Latino	24	21	23
Unknown or Not Reported	4	3	6

Reporting group values	Total		
Number of subjects	324		
Age categorical			
Units: Subjects			
Adults (18-64 years)	201		
From 65-84 years	121		
85 years and over	2		
Age Continuous			
Units: Years			
arithmetic mean			
full range (min-max)	-		
Sex: Female, Male			
Units: Participants			
Female	133		
Male	191		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	18		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	13		
White	282		
More than one race	0		
Unknown or Not Reported	11		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	27		
Not Hispanic or Latino	250		
Unknown or Not Reported	47		

End points

End points reporting groups

Reporting group title	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI
Reporting group description: First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer	
Reporting group title	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI
Reporting group description: First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer	
Reporting group title	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB
Reporting group description: First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer	
Reporting group title	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Reporting group description: First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE)	
Reporting group title	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer	
Reporting group title	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO
Reporting group description: Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer	
Reporting group title	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO
Reporting group description: Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer	
Reporting group title	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI
Reporting group description: Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer	
Reporting group title	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Reporting group description: Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer	
Reporting group title	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI
Reporting group description: Second-line treatment FOLFIRI in participants with colorectal cancer	

Reporting group title	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB
Reporting group description: First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer	
Reporting group title	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO
Reporting group description: First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer	
Reporting group title	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Reporting group description: First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer	
Reporting group title	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO
Reporting group description: Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer	
Reporting group title	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO
Reporting group description: Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer	

Primary: Number of Participants Experiencing Adverse Events (AEs)

End point title	Number of Participants Experiencing Adverse Events (AEs) ^[1]
End point description: An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Adverse events are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.	
End point type	Primary
End point timeframe: From first dose up to 100 days post last dose, up to approximately 3 years	
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: Summary statistics only were planned for this endpoint	

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants	10	8	10	11

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants	8	7	7	11

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants	1	2	32	32

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Participants	25	35	35	31

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants	23	32		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Serious Adverse Events (SAEs)

End point title	Number of Participants Experiencing Serious Adverse Events (SAEs) ^[2]
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End point description:

A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe), requires inpatient hospitalization or causes prolongation of existing hospitalization.

End point type	Primary
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End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

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: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants	5	5	5	7

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants	5	6	6	6

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants	1	2	12	12

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Participants	6	24	22	15

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants	17	19		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Dose-Limiting Toxicities (DLTs)

End point title	Number of Participants Experiencing Dose-Limiting Toxicities (DLTs) ^[3]
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End point description:

Dose-limiting toxicities (DLTs) are severe adverse effects (AEs) that are attributed to BMS-813160 or the combination regimen and define the maximum tolerated dose of a medicine. DLTs will be defined based on the incidence, duration and grade of AEs for which no alternate cause can be identified. AEs will be evaluated according to the NCI CTCAE v4.03. The incidence of DLT(s) during the first 6 weeks of treatment in Part 1 (the DLT evaluation period) and 4 weeks for Part 2 will be used.

End point type	Primary
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End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

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

Justification: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BI D + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600Q D + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants	0	0	2	2

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants	0	0	0	0

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants	0	0	0	0

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Participants	0	0	1	0

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

End point title	Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation ^[4]
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End point description:

An Adverse Event (AE) leading to discontinuation is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment that leads to the discontinuation of study treatment. Adverse events are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.

End point type	Primary
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End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

[4] - 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: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants	2	0	1	6

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants	0	1	0	1

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants	0	1	10	6

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Participants	2	12	8	3

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants	4	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who Died

End point title	Number of Participants who Died ^[5]
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End point description:

The number of participants who died within 100 days of the last dose of treatment

End point type	Primary
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End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

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

Justification: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants	6	6	8	8

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants	6	6	6	7

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants	1	2	26	28

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32

Units: Participants	17	33	34	26
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End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants	20	25		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Laboratory Abnormalities

End point title	Number of Participants Experiencing Laboratory
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End point description:

The number of participants experiencing laboratory abnormalities in pre-specified selected parameters during the treatment period per CTCAE (Version 4). Laboratory abnormalities are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.

End point type	Primary
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End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

[6] - 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: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A- Cohort 1: 1L CRC/BMS300BI D + FOLFIRI	Part 1-Arm A- Cohort 2: 1L CRC/BMS600Q D + FOLFIRI	Part 1-Arm B- Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B- Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants				
ALT (U/L) - Abnormal High	2	4	5	7
AST (U/L) - Abnormal High	2	4	5	7
Total Bilirubin (UMOL/L) - Abnormal High	2	4	5	2
Neutrophils (Absolute) (10 ⁹ /L) - Abnormal Low	6	4	5	9
PLATELET COUNT (10 ⁹ /L) - Abnormal Low	5	1	5	5

End point values	Part 1-Arm C-	Part 1-Arm C-	Part 1-Arm C-	Part 1-Arm C-
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	Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Chort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Chort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants				
ALT (U/L) - Abnormal High	2	1	3	6
AST (U/L) - Abnormal High	3	3	5	5
Total Bilirubin (UMOL/L) - Abnormal High	1	1	4	3
Neutrophils (Absolute) (10 ⁹ /L) - Abnormal Low	2	1	1	2
PLATELET COUNT (10 ⁹ /L) - Abnormal Low	2	1	1	3

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants				
ALT (U/L) - Abnormal High	1	1	15	9
AST (U/L) - Abnormal High	1	1	15	12
Total Bilirubin (UMOL/L) - Abnormal High	1	1	5	5
Neutrophils (Absolute) (10 ⁹ /L) - Abnormal Low	0	0	25	20
PLATELET COUNT (10 ⁹ /L) - Abnormal Low	0	0	11	15

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Participants				
ALT (U/L) - Abnormal High	10	24	28	24
AST (U/L) - Abnormal High	9	21	26	24
Total Bilirubin (UMOL/L) - Abnormal High	2	8	7	5
Neutrophils (Absolute) (10 ⁹ /L) - Abnormal Low	18	22	25	25
PLATELET COUNT (10 ⁹ /L) - Abnormal Low	8	24	28	26

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants				
ALT (U/L) - Abnormal High	10	13		
AST (U/L) - Abnormal High	12	19		
Total Bilirubin (UMOL/L) - Abnormal High	6	7		
Neutrophils (Absolute) (10 ⁹ /L) - Abnormal Low	1	4		
PLATELET COUNT (10 ⁹ /L) - Abnormal Low	10	5		

Statistical analyses

No statistical analyses for this end point

Primary: Vital Signs

End point title	Vital Signs ^[7]
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End point description:

Vital sign measurements at baseline and at the end of treatment. Vital signs measurements include systolic blood pressure and diastolic blood pressure.

"99999"=N/A

End point type	Primary
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End point timeframe:

From first dose to 100 days post last dose, up to approximately 3 years

Notes:

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

Justification: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A- Cohort 1: 1L CRC/BMS300BI D + FOLFIRI	Part 1-Arm A- Cohort 2: 1L CRC/BMS600Q D + FOLFIRI	Part 1-Arm B- Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B- Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	9	11
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure (mmHg) - Follow-up	140.0 (± 8.5)	124.5 (± 2.1)	100.0 (± 99999)	143.0 (± 34.0)
Systolic Blood Pressure (mmHg) - End of Treatment	133.0 (± 99999)	129.7 (± 6.7)	130.2 (± 21.8)	143.0 (± 34.0)
Diastolic Blood Pressure (mmHg) - Follow-up	79.0 (± 99999)	71.5 (± 14.8)	59.0 (± 99999)	99999 (± 99999)
Diastolic Blood Pressure (mmHg) - End of Treatment	83.0 (± 99999)	73.3 (± 7.2)	75.4 (± 12.4)	80.8 (± 17.7)

End point values	Part 1-Arm C- Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Part 1-Arm C- Cohort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Part 1-Arm C- Cohort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Part 1-Arm C- Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	7	10
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure (mmHg) - Follow-up	140.0 (± 8.5)	108.0 (± 99999)	148.0 (± 99999)	129.5 (± 29.0)
Systolic Blood Pressure (mmHg) - End of Treatment	114.0 (± 15.0)	125.0 (± 6.1)	140.3 (± 18.0)	124.0 (± 23.7)
Diastolic Blood Pressure (mmHg) - Follow-up	85.0 (± 2.8)	69.0 (± 99999)	98.0 (± 99999)	72.5 (± 4.9)
Diastolic Blood Pressure (mmHg) - End of Treatment	69.6 (± 9.4)	86.0 (± 18.2)	89.7 (± 11.1)	74.3 (± 11.3)

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	31
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure (mmHg) - Follow-up	99999 (± 99999)	99999 (± 99999)	127.9 (± 13.2)	131.3 (± 20.6)
Systolic Blood Pressure (mmHg) - End of Treatment	151.0 (± 99999)	107.0 (± 99999)	126.0 (± 15.9)	113.0 (± 99999)
Diastolic Blood Pressure (mmHg) - Follow-up	99999 (± 99999)	99999 (± 99999)	76.6 (± 14.6)	76.1 (± 11.0)
Diastolic Blood Pressure (mmHg) - End of Treatment	86.0 (± 99999)	67.0 (± 99999)	79.0 (± 11.5)	74.5 (± 3.5)

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	34	34	32
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure (mmHg) - Follow-up	127.3 (± 14.4)	130.7 (± 22.6)	133.9 (± 15.9)	127.1 (± 18.2)
Systolic Blood Pressure (mmHg) - End of Treatment	113.0 (± 99999)	123.2 (± 18.8)	128.9 (± 17.8)	118.8 (± 15.9)
Diastolic Blood Pressure (mmHg) - Follow-up	78.2 (± 7.3)	68.0 (± 9.9)	70.2 (± 10.5)	66.7 (± 20.1)

Diastolic Blood Pressure (mmHg) - End of Treatment	75.0 (± 99999)	69.2 (± 8.2)	74.3 (± 8.6)	70.2 (± 8.6)
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End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	31		
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure (mmHg) - Follow-up	121.3 (± 16.3)	128.1 (± 20.3)		
Systolic Blood Pressure (mmHg) - End of Treatment	112.6 (± 11.6)	123.1 (± 13.6)		
Diastolic Blood Pressure (mmHg) - Follow-up	85.0 (± 99999)	69.0 (± 2.8)		
Diastolic Blood Pressure (mmHg) - End of Treatment	68.1 (± 6.5)	74.3 (± 9.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Out-of-Range Electrocardiograms (ECG)

End point title	Number of Participants with Out-of-Range Electrocardiograms (ECG) ^[8]
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End point description:

The number of participants with ECG measurements outside of the range pre-specified in the protocol.

End point type	Primary
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End point timeframe:

From baseline up to 100 days post last dose

Notes:

[8] - 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: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A- Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A- Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B- Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B- Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	10
Units: Participants				
QTcF INTERVAL (MSEC) < 450	7	8	10	8
QTcF INTERVAL (MSEC): 450 <= QTcF < 480	3	0	0	1
480<=QTcF<500 (MSEC)	0	0	0	1
QTcF>= 500 (MSEC)	0	0	0	0
QTcB INTERVAL (MSEC) < 450	4	7	8	5

450<=QTcB<480 (MSEC)	5	1	1	3
480<=QTcB<500 (MSEC)	1	0	1	2
QTcB>= 500 (MSEC)	0	0	0	0

End point values	Part 1-Arm C- Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Part 1-Arm C- Cohort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Part 1-Arm C- Cohort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Part 1-Arm C- Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants				
QTcF INTERVAL (MSEC) < 450	8	7	7	10
QTcF INTERVAL (MSEC): 450 <= QTcF < 480	0	0	0	1
480<=QTcF<500 (MSEC)	0	0	0	0
QTcF>= 500 (MSEC)	0	0	0	0
QTcB INTERVAL (MSEC) < 450	7	3	3	7
450<=QTcB<480 (MSEC)	1	4	3	2
480<=QTcB<500 (MSEC)	0	0	1	2
QTcB>= 500 (MSEC)	0	0	0	0

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	31
Units: Participants				
QTcF INTERVAL (MSEC) < 450	1	2	31	27
QTcF INTERVAL (MSEC): 450 <= QTcF < 480	0	0	0	4
480<=QTcF<500 (MSEC)	0	0	0	0
QTcF>= 500 (MSEC)	0	0	1	0
QTcB INTERVAL (MSEC) < 450	1	2	20	21
450<=QTcB<480 (MSEC)	0	0	11	7
480<=QTcB<500 (MSEC)	0	0	0	3
QTcB>= 500 (MSEC)	0	0	1	0

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	34	34	29
Units: Participants				
QTcF INTERVAL (MSEC) < 450	23	26	30	26

QTcF INTERVAL (MSEC): 450 <= QTcF < 480	2	6	4	3
480<=QTcF<500 (MSEC)	0	1	0	0
QTcF>= 500 (MSEC)	0	1	0	0
QTcB INTERVAL (MSEC) < 450	15	14	17	19
450<=QTcB<480 (MSEC)	10	14	14	8
480<=QTcB<500 (MSEC)	0	4	3	2
QTcB>= 500 (MSEC)	0	2	0	0

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants				
QTcF INTERVAL (MSEC) < 450	24	31		
QTcF INTERVAL (MSEC): 450 <= QTcF < 480	0	2		
480<=QTcF<500 (MSEC)	0	0		
QTcF>= 500 (MSEC)	0	0		
QTcB INTERVAL (MSEC) < 450	21	15		
450<=QTcB<480 (MSEC)	3	18		
480<=QTcB<500 (MSEC)	0	0		
QTcB>= 500 (MSEC)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change in Regulatory T Cells (Treg) and Tumor-Associated Macrophages (TAMs) in Tumor Samples

End point title	Percent Change in Regulatory T Cells (Treg) and Tumor-Associated Macrophages (TAMs) in Tumor Samples ^[9]
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End point description:

The percent change in Regulatory T Cells (Treg) and Tumor-Associated Macrophages (TAMs) were taken at prespecified timepoints. Baseline is defined as the last non-missing value prior to the first dosing.

"99999"=N/A

End point type	Primary
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End point timeframe:

From first dose up to prespecified timepoints

Notes:

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

Justification: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Percent change				
median (full range (min-max))				
CD163 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C0D7	26.6 (-67 to 180)	-43.8 (-58 to 15)	-22.9 (-74 to 14)	156.4 (-12 to 177)
FOXP3 - C0D14	26.5 (-50 to 103)	-19.8 (-78 to 53)	60.0 (60 to 60)	-41.6 (-67 to 16)
FOXP3 - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11

Units: Percent change				
median (full range (min-max))				
CD163 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	13.1 (2 to 808)	-12.7 (-67 to 231)
CD163 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	95.4 (34 to 157)	133.6 (0 to 286)
CD163 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	477.5 (334 to 621)	22.1 (-28 to 520)
CD163 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	7.6 (-37 to 53)	-93 (-93 to -93)
CD163 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	-70.2 (-91 to 107)	-17.1 (-64 to -2)
CD68 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	57.7 (-12 to 128)	7.9 (-8 to 24)
CD68 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	294.2 (203 to 385)	17.8 (-39 to 102)
CD68 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	2.9 (-26 to 185)	-26 (-26 to -26)
CD68 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C0D7	57.3 (-76 to 116)	-18.4 (-27 to -9)	-92.2 (-94 to 27)	96.4 (14 to 152)
FOXP3 - C0D14	-41 (-41 to -41)	-26.5 (-57 to 249)	180.2 (-60 to 421)	-3.7 (-9 to 25)
FOXP3 - C1D1	34.7 (-58 to 128)	49 (49 to 49)	147.4 (20 to 275)	33.0 (-51 to 338)
FOXP3 - C1D15	-25.9 (-48 to -6)	14.5 (-90 to 322)	39.1 (4 to 74)	-33 (-33 to -33)
FOXP3 - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Percent change				
median (full range (min-max))				
CD163 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

CD163 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	89.8 (35 to 132)
CD163 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	1369 (1369 to 1369)	99999 (99999 to 99999)
CD163 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	-4.1 (-21 to 1072)	-58.4 (-98 to -19)
CD163 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	-58.3 (-94 to -22)	99999 (99999 to 99999)
CD68 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	-4.0 (-27 to 58)
CD68 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	272 (272 to 272)	99999 (99999 to 99999)
CD68 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	31.5 (-60 to 296)	-70.7 (-92 to -49)
CD68 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	-26.9 (-50 to -4)	99999 (99999 to 99999)
FOXP3 - C0D7	99999 (99999 to 99999)	101.0 (101 to 101)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D1	99999 (99999 to 99999)	31.0 (31 to 31)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	-39.1 (-46 to -32)
FOXP3 - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	-21 (-21 to -21)	99999 (99999 to 99999)
FOXP3 - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)	-7.4 (-26 to 113)	-77.0 (-93 to -61)
FOXP3 - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	305.2 (-73 to 683)	99999 (99999 to 99999)

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Percent change				
median (full range (min-max))				
CD163 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD163 Positive - C1D15	-61 (-61 to -61)	145.7 (43 to 248)	99999 (99999 to 99999)	60.3 (1 to 120)
CD163 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

CD163 Positive - C1D28	106.3 (-67 to 511)	-14.7 (-57 to 91)	65.5 (-31 to 666)	1.0 (-96 to 61)
CD163 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	-41.3 (-61 to -33)
CD68 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D15	81 (81 to 81)	162.4 (150 to 175)	99999 (99999 to 99999)	92.5 (20 to 165)
CD68 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
CD68 Positive - C1D28	96.2 (-50 to 1106)	-38.3 (-88 to 121)	96.2 (-25 to 179)	-4.3 (-46 to 102)
CD68 Positive - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	-40.0 (-54 to -33)
FOXP3 - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D15	60 (60 to 60)	113.6 (-1 to 228)	99999 (99999 to 99999)	17.0 (-39 to 73)
FOXP3 - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
FOXP3 - C1D28	12.0 (-73 to 152)	-36.0 (-77 to -5)	99.4 (-96 to 2199)	-46.6 (-55 to 551)
FOXP3 - C2D1	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	184 (184 to 184)

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Percent change				
median (full range (min-max))				
CD163 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD163 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD163 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD163 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD163 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD163 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD163 Positive - C2D1	99999 (99999 to 99999)	39.3 (-1 to 79)		
CD68 Positive - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)		

CD68 Positive - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD68 Positive - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD68 Positive - C1D15	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD68 Positive - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD68 Positive - C1D28	99999 (99999 to 99999)	99999 (99999 to 99999)		
CD68 Positive - C2D1	99999 (99999 to 99999)	-66 (-66 to -66)		
FOXP3 - C0D7	99999 (99999 to 99999)	99999 (99999 to 99999)		
FOXP3 - C0D14	99999 (99999 to 99999)	99999 (99999 to 99999)		
FOXP3 - C1D1	99999 (99999 to 99999)	99999 (99999 to 99999)		
FOXP3 - C1D15	-64 (-64 to -64)	99999 (99999 to 99999)		
FOXP3 - C1D16	99999 (99999 to 99999)	99999 (99999 to 99999)		
FOXP3 - C1D28	216.7 (98 to 363)	-13.6 (-78 to 149)		
FOXP3 - C2D1	-2.4 (-37 to 32)	156.2 (13 to 299)		

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR) ^[10]
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End point description:

Objective Response Rate (ORR) as determined by Investigator was defined as the number of participants with a best overall response of confirmed Complete Response (CR) or Partial Response (PR) (per RECIST 1.1 criteria) divided by the number of all treated participants. Progression is defined as at least 20% increase in the sum of diameters of target lesions and an absolute increase of at least 5 mm.

RECIST 1.1 = Response Evaluation Criteria in Solid Tumors. Complete response (CR)= Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. Partial response (PR)= At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Primary
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End point timeframe:

From first dose until disease progression, or the last response recorded, approximately 3 years

Notes:

[10] - 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: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Percent of participants				
number (confidence interval 95%)	60.0 (26.2 to 87.8)	25.0 (3.2 to 65.1)	0 (0.0 to 30.8)	18.2 (2.3 to 51.8)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Percent of participants				
number (confidence interval 95%)	0 (0.0 to 36.9)	0 (0.0 to 41.0)	0 (0.0 to 41.0)	0 (0.0 to 28.5)

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Percent of participants				
number (confidence interval 95%)	0 (0.0 to 97.5)	0 (0.0 to 84.2)	9.4 (2.0 to 25.0)	9.4 (2.0 to 25.0)

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Percent of participants				
number (confidence interval 95%)	19.2 (6.6 to 39.4)	22.9 (10.4 to 40.1)	17.1 (6.6 to 33.6)	21.9 (9.3 to 40.0)

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS/BMS300BID + NIVO		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: Percent of participants				
number (confidence interval 95%)	0 (0.0 to 14.2)	8.3 (1.0 to 27.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Response (DoR)

End point title	Duration of Response (DoR) ^[11]
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End point description:

Duration of Response (DOR), computed for all treated participants with a best overall response (BOR) of complete response (CR) or partial response (PR), is defined as the time between the date of first response (CR or PR) and the date of first documented disease progression as determined by RECIST 1.1 or death due to any cause, whichever occurs first, ie., DOR = disease progression date/death date -first response date + 1. For participants who remain alive and have not progressed, DOR will be censored on the date of their last tumor assessment.

CR= Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. PR= At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

"99999"=N/A

End point type	Primary
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End point timeframe:

From first response up to date of disease progression or death, whichever occurs first (up to approximately 5 years)

Notes:

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

Justification: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	0 ^[12]	2
Units: Weeks				
median (confidence interval 95%)	159.00 (47.00 to 99999)	99999 (16.43 to 99999)	(to)	99999 (24.14 to 99999)

Notes:

[12] - Median, lower, and upper limited not calculated due to insufficient number of events

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[13]	0 ^[14]	0 ^[15]	0 ^[16]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[13] - Median, lower, and upper limited not calculated due to insufficient number of events

[14] - Median, lower, and upper limited not calculated due to insufficient number of events

[15] - Median, lower, and upper limited not calculated due to insufficient number of events

[16] - Median, lower, and upper limited not calculated due to insufficient number of events

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[17]	0 ^[18]	3	3
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	74.14 (32.14 to 99999)	56.57 (40.17 to 99999)

Notes:

[17] - Median, lower, and upper limited not calculated due to insufficient number of events

[18] - Median, lower, and upper limited not calculated due to insufficient number of events

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	6	7
Units: Weeks				
median (confidence interval 95%)	36.21 (16.14 to 99999)	32.14 (17.14 to 37.29)	37.14 (14.14 to 99999)	20.57 (14.29 to 31.00)

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[19]	2		
Units: Weeks				
median (confidence interval 95%)	(to)	99999 (41.00 to 99999)		

Notes:

[19] - Median, lower, and upper limited not calculated due to insufficient number of events

Statistical analyses

No statistical analyses for this end point

Primary: Progression Free Survival (PFS) Rate at 24 Weeks

End point title	Progression Free Survival (PFS) Rate at 24 Weeks ^[20]
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End point description:

PFS rate is defined as the percentage of participants who were progression free at Week 24. PFS is defined as the time from first dose to the date of first objectively documented disease progression or death due to any cause, whichever occurs first. Progression is defined as at least a 20% increase in the sum of diameters of target lesions and an absolute increase of at least 5 mm.

Complete response (CR)= Disappearance of all target lesions. Pathological lymph nodes must have short axis reduction to < 10 mm. Partial response (PR)= At least 30% decrease in sum of diameters of target lesions.

Participants who died w/o prior progression were considered progressed on death date. Those alive and not progressed were censored on the last tumor assessment date. Those who started subsequent therapy without reported progression were censored at last tumor assessment prior to subsequent therapy. Those without post-baseline tumor assessment and alive were censored at first dose.

End point type	Primary
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End point timeframe:

From first dose up to Week 24

Notes:

[20] - 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: Summary statistics only were planned for this endpoint

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	4	5	6
Units: Percentage of Participants				
number (confidence interval 95%)	0.778 (0.3648 to 0.9393)	99999 (99999 to 99999)	0.556 (0.2042 to 0.8045)	0.800 (0.4087 to 0.9459)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[21]	0 ^[22]	0 ^[23]	1
Units: Percentage of Participants				
number (confidence interval 95%)	(to)	(to)	(to)	99999 (99999 to 99999)

Notes:

[21] - Not calculated due to insufficient number of events

[22] - Not calculated due to insufficient number of events

[23] - Not calculated due to insufficient number of events

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[24]	0 ^[25]	7	14
Units: Percentage of Participants				
number (confidence interval 95%)	(to)	(to)	0.357 (0.1699 to 0.5490)	0.536 (0.3372 to 0.6996)

Notes:

[24] - Not calculated due to insufficient number of events

[25] - Not calculated due to insufficient number of events

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	21	13
Units: Percentage of Participants				
number (confidence interval 95%)	0.691 (0.4361 to 0.8478)	0.535 (0.3512 to 0.6888)	0.636 (0.4495 to 0.7746)	0.467 (0.2779 to 0.6358)

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[26]	3		
Units: Percentage of Participants				
number (confidence interval 95%)	(to)	99999 (99999 to 99999)		

Notes:

[26] - Not calculated due to insufficient number of events

Statistical analyses

No statistical analyses for this end point

Secondary: Maximim Concentration (Cmax)

End point title	Maximim Concentration (Cmax)
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End point description:

Cmax is defined as the maximum plasma concentration of the analytes at the prespecified timepoints.

"99999"=N/A

End point type	Secondary
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End point timeframe:

From first dose up to the prespecified timepoints, C0D1, C0D14, AND C2D1

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	10
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	620.4 (± 250.60)	2204.1 (± 961.90)	828.4 (± 458.03)	2419.0 (± 1203.53)
C0D1 - BMS-939429	172.23 (± 103.837)	435.6 (± 284.14)	207.63 (± 142.559)	545.7 (± 218.89)

C0D14 - BMS-813160	927.1 (± 513.88)	4152.5 (± 2010.23)	1060.3 (± 830.04)	3274.0 (± 884.15)
C0D14 - BMS-939429	317.90 (± 290.209)	658.3 (± 143.17)	409.63 (± 382.471)	792.2 (± 503.92)
C2D1 - BMS-813160	1153.1 (± 617.97)	3280.0 (± 777.82)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-939429	254.1 (± 140.73)	571.0 (± 376.42)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	6
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	486.3 (± 137.69)	1896.3 (± 1421.89)	1179.1 (± 605.50)	276.28 (± 141.915)
C0D1 - BMS-939429	92.33 (± 50.015)	539.1 (± 465.93)	237.63 (± 188.286)	54.82 (± 23.716)
C0D14 - BMS-813160	701.5 (± 284.59)	1793.5 (± 1607.25)	653.3 (± 298.08)	80.00 (± 19.408)
C0D14 - BMS-939429	183.08 (± 190.050)	326.0 (± 241.83)	165.83 (± 92.914)	25.307 (± 16.6021)
C2D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BI D + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	18	15
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	1580.0 (± 99999)	807.0 (± 99999)	99999 (± 99999)	99999 (± 99999)
C0D1 - BMS-939429	504.0 (± 99999)	72.50 (± 99999)	99999 (± 99999)	99999 (± 99999)
C0D14 - BMS-813160	1370.0 (± 99999)	1680.0 (± 961.67)	99999 (± 99999)	99999 (± 99999)
C0D14 - BMS-939429	498.0 (± 99999)	265.40 (± 235.608)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	903.9 (± 578.56)	357.55 (± 264.384)
C2D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[27]	20	0 ^[28]	0 ^[29]
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	99999 (± 99999)	()	()
C0D1 - BMS-939429	()	99999 (± 99999)	()	()
C0D14 - BMS-813160	()	99999 (± 99999)	()	()
C0D14 - BMS-939429	()	99999 (± 99999)	()	()
C2D1 - BMS-813160	()	796.2 (± 472.48)	()	()
C2D1 - BMS-939429	()	99999 (± 99999)	()	()

Notes:

[27] - Cmax not calculated because there was an insufficient number of participants with evaluable data

[28] - Cmax not calculated because there was an insufficient number of participants with evaluable data

[29] - Cmax not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[30]	0 ^[31]		
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	()		
C0D1 - BMS-939429	()	()		
C0D14 - BMS-813160	()	()		
C0D14 - BMS-939429	()	()		
C2D1 - BMS-813160	()	()		
C2D1 - BMS-939429	()	()		

Notes:

[30] - Cmax not calculated because there was an insufficient number of participants with evaluable data

[31] - Cmax not calculated because there was an insufficient number of participants with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Concentration (Tmax)

End point title	Time to Maximum Concentration (Tmax)
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End point description:

Tmax is defined as the time in hours of the maximum observed plasma concentration

End point type	Secondary
End point timeframe:	
From first dose up to the prespecified timepoints, C0D1, C0D14, AND C2D1	

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	10
Units: Hours				
median (full range (min-max))				
C0D1 - BMS-813160	2.000 (0.50 to 4.00)	0.500 (0.47 to 4.00)	3.017 (2.00 to 4.02)	2.492 (0.73 to 5.98)
C0D1 - BMS-939429	3.500 (0.50 to 6.25)	1.000 (0.50 to 4.00)	3.508 (1.00 to 11.98)	3.000 (0.73 to 5.98)
C0D14 - BMS-813160	3.000 (0.55 to 3.03)	1.825 (0.50 to 3.00)	2.917 (0.92 to 15.70)	2.983 (0.50 to 4.00)
C0D14 - BMS-939429	3.000 (0.98 to 4.00)	1.825 (0.50 to 3.00)	3.000 (1.08 to 15.70)	2.983 (1.00 to 4.00)
C2D1 - BMS-813160	3.000 (0.98 to 4.23)	1.000 (0.47 to 4.03)	99999 (99999 to 99999)	99999 (99999 to 99999)
C2D1 - BMS-939429	3.000 (2.00 to 4.23)	1.000 (0.97 to 4.03)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	6
Units: Hours				
median (full range (min-max))				
C0D1 - BMS-813160	2.492 (0.52 to 11.92)	2.983 (0.58 to 8.92)	3.00 (0.50 to 6.00)	1.992 (0.50 to 3.00)
C0D1 - BMS-939429	3.000 (1.0 to 11.92)	2.083 (1.08 to 8.92)	3.000 (1.00 to 6.00)	2.000 (0.98 to 4.00)
C0D14 - BMS-813160	2.875 (0.50 to 3.00)	2.0 (1 to 3)	2.000 (1.00 to 3.02)	1.00 (0.5 to 4.0)
C0D14 - BMS-939429	2.875 (1.17 to 3.00)	2.492 (1.98 to 3.00)	3.000 (1.00 to 4.02)	1.0 (1 to 6)
C2D1 - BMS-813160	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
C2D1 - BMS-939429	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD
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	+ NIVO	+ NIVO	D + FOLFIRI	D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	18	15
Units: Hours				
median (full range (min-max))				
C0D1 - BMS-813160	2.0 (2 to 2)	3.950 (3.95 to 3.95)	99999 (99999 to 99999)	99999 (99999 to 99999)
C0D1 - BMS-939429	2.0 (2 to 2)	1.950 (1.95 to 1.95)	99999 (99999 to 99999)	99999 (99999 to 99999)
C0D14 - BMS-813160	2.02 (2.02 to 2.02)	2.542 (2.00 to 3.08)	99999 (99999 to 99999)	99999 (99999 to 99999)
C0D14 - BMS-939429	2.02 (2.02 to 2.02)	3.117 (2.00 to 4.23)	99999 (99999 to 99999)	99999 (99999 to 99999)
C2D1 - BMS-813160	99999 (99999 to 99999)	99999 (99999 to 99999)	2.033 (0.50 to 14.10)	2.067 (0.50 to 8.10)
C2D1 - BMS-939429	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[32]	20	0 ^[33]	0 ^[34]
Units: Hours				
median (full range (min-max))				
C0D1 - BMS-813160	(to)	99999 (99999 to 99999)	(to)	(to)
C0D1 - BMS-939429	(to)	99999 (99999 to 99999)	(to)	(to)
C0D14 - BMS-813160	(to)	99999 (99999 to 99999)	(to)	(to)
C0D14 - BMS-939429	(to)	99999 (99999 to 99999)	(to)	(to)
C2D1 - BMS-813160	(to)	3.992 (0.50 to 16.17)	(to)	(to)
C2D1 - BMS-939429	(to)	99999 (99999 to 99999)	(to)	(to)

Notes:

[32] - Tmax not calculated because there was an insufficient number of participants with evaluable data

[33] - Tmax not calculated because there was an insufficient number of participants with evaluable data

[34] - Tmax not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[35]	0 ^[36]		
Units: Hours				
median (full range (min-max))				
C0D1 - BMS-813160	(to)	(to)		
C0D1 - BMS-939429	(to)	(to)		

C0D14 - BMS-813160	(to)	(to)		
C0D14 - BMS-939429	(to)	(to)		
C2D1 - BMS-813160	(to)	(to)		
C2D1 - BMS-939429	(to)	(to)		

Notes:

[35] - Tmax not calculated because there was an insufficient number of participants with evaluable data

[36] - Tmax not calculated because there was an insufficient number of participants with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Observed Plasma Concentration (Ctrough)

End point title	Trough Observed Plasma Concentration (Ctrough)
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End point description:

Ctrough is defined as the concentration reached by a drug immediately before the next dose is administered

"99999"=N/A

End point type	Secondary
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End point timeframe:

From first dose up to prespecified timepoints, C0D1, C5D1, C0D1, C1D15, C5D1

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	3	4	4
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	283.70 (± 207.784)	84.30 (± 46.169)	292.0 (± 154.31)	74.05 (± 72.127)
C5D1 - BMS-813160	268.80 (± 216.882)	129.40 (± 89.944)	176.0 (± 99999)	15.30 (± 99999)
C0D1 - BMS-939429	172.63 (± 264.187)	31.40 (± 10.689)	180.88 (± 195.959)	72.95 (± 55.542)
C1D15 - BMS 939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C5D1 - BMS-939429	55.78 (± 31.877)	15.95 (± 4.172)	155.0 (± 99999)	10.50 (± 99999)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	1	2	2
Units: ng/mL				
arithmetic mean (standard deviation)				

C0D1 - BMS-813160	157.28 (± 92.311)	137.0 (± 99999)	57.10 (± 54.871)	5.485 (± 2.4395)
C5D1 - BMS-813160	323.0 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C0D1 - BMS-939429	47.60 (± 10.412)	31.50 (± 99999)	63.45 (± 60.175)	4.950 (± 2.3052)
C1D15 - BMS 939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C5D1 - BMS-939429	65.20 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	11	16
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	77.40 (± 99999)	154.05 (± 139.936)	99999 (± 99999)	99999 (± 99999)
C5D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C0D1 - BMS-939429	90.30 (± 99999)	71.65 (± 55.649)	99999 (± 99999)	99999 (± 99999)
C1D15 - BMS 939429	99999 (± 99999)	99999 (± 99999)	191.33 (± 84.266)	24.106 (± 18.445)
C5D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)	186.21 (± 131.457)	12.439 (± 6.9685)

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	7	6	0 ^[37]
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	()
C5D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	()
C0D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	()
C1D15 - BMS 939429	275.7 (± 164.34)	116.04 (± 29.696)	145.00 (± 99.293)	()
C5D1 - BMS-939429	195.0 (± 99999)	191.44 (± 113.725)	222.65 (± 154.316)	()

Notes:

[37] - Ctrough not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C-	Part 2-Arm C-		
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	Cohort 4: 2L PC/BMS300BID + NIVO	Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: ng/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)		
C5D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)		
C0D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)		
C1D15 - BMS 939429	283.0 (± 99999)	99999 (± 99999)		
C5D1 - BMS-939429	99999 (± 99999)	390.0 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Curve (AUC) 0-8

End point title	Area Under Curve (AUC) 0-8
End point description:	
Area Under Curve (AUC) is defined as the area under the plot of plasma concentration of a drug versus time after dosage measured at 8 hours post-dose	
"99999"=N/A	
End point type	Secondary
End point timeframe:	
From first dose up to prespecified timepoints- C0D1, C2D1	

End point values	Part 1-Arm A- Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A- Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B- Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B- Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	10	10
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	2300.018 (± 976.4608)	7069.265 (± 2452.4213)	2725.390 (± 1365.3562)	7884.381 (± 3968.4940)
C0D1 - BMS-939429	652.848 (± 363.5925)	1783.336 (± 856.0103)	936.394 (± 826.5807)	2302.092 (± 1023.3978)
C2D1 - BMS-813160	5348.973 (± 2506.2558)	11967.560 (± 4586.3823)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-939429	1410.415 (± 837.4895)	2403.182 (± 1144.3271)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C- Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Part 1-Arm C- Cohort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Part 1-Arm C- Cohort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Part 1-Arm C- Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	6
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	1534.932 (± 518.2172)	6593.904 (± 3603.5286)	3533.737 (± 1931.7752)	878.051 (± 535.3197)
C0D1 - BMS-939429	342.534 (± 157.1350)	2147.888 (± 1415.6386)	942.398 (± 620.1018)	210.938 (± 106.5352)
C2D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	9	13
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	4440.313 (± 99999)	3656.713 (± 99999)	99999 (± 99999)	99999 (± 99999)
C0D1 - BMS-939429	1919.228 (± 99999)	411.410 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	4838.264 (± 2750.7756)	1483.423 (± 1236.0374)
C2D1 - BMS-939429	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[38]	14	0 ^[39]	0 ^[40]
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	99999 (± 99999)	()	()
C0D1 - BMS-939429	()	99999 (± 99999)	()	()
C2D1 - BMS-813160	()	3821.887 (± 2221.2474)	()	()

C2D1 - BMS-939429	()	99999 (± 99999)	()	()
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Notes:

[38] - AUC not calculated because there was an insufficient number of participants with evaluable data

[39] - AUC not calculated because there was an insufficient number of participants with evaluable data

[40] - AUC not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0 ^[41]		
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	99999 (± 99999)	()		
C0D1 - BMS-939429	99999 (± 99999)	()		
C2D1 - BMS-813160	99999 (± 99999)	()		
C2D1 - BMS-939429	99999 (± 99999)	()		

Notes:

[41] - AUC not calculated because there was an insufficient number of participants with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Curve (AUC) 0-24

End point title	Area Under Curve (AUC) 0-24
End point description:	
Area Under Curve (AUC) is defined as the area under the plot of plasma concentration of a drug versus time after dosage measured at 8 hours post-dose	
End point type	Secondary
End point timeframe:	
From first dose up to prespecified timepoints-C0D1, C2D1	

End point values	Part 1-Arm A- Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A- Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B- Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B- Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[42]	7	0 ^[43]	9
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	9383.385 (± 2842.8397)	()	11726.669 (± 6439.1376)
C0D1 - BMS-939429	()	2638.062 (± 977.2502)	()	3991.522 (± 1636.3573)

C2D1 - BMS-813160	()	17890.458 (± 9212.5646)	()	99999 (± 99999)
C2D1 - BMS-939429	()	3958.779 (± 1632.3781)	()	99999 (± 99999)

Notes:

[42] - AUC not calculated because there was an insufficient number of participants with evaluable data

[43] - AUC not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[44]	5	7	6
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	10447.179 (± 2995.9347)	4829.881 (± 2696.4668)	1275.314 (± 799.8262)
C0D1 - BMS-939429	()	3905.941 (± 1852.8415)	1660.159 (± 991.0121)	341.0396 (± 160.4425)
C2D1 - BMS-813160	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-939429	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[44] - AUC not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[45]	1	0 ^[46]	11
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	7687.658 (± 99999)	()	99999 (± 99999)
C0D1 - BMS-939429	()	940.294 (± 99999)	()	99999 (± 99999)
C2D1 - BMS-813160	()	99999 (± 99999)	()	2050.804 (± 997.6990)
C2D1 - BMS-939429	()	99999 (± 99999)	()	99999 (± 99999)

Notes:

[45] - AUC not calculated because there was an insufficient number of participants with evaluable data

[46] - AUC not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[47]	0 ^[48]	0 ^[49]	0 ^[50]
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	()	()	()

C0D1 - BMS-939429	()	()	()	()
C2D1 - BMS-813160	()	()	()	()
C2D1 - BMS-939429	()	()	()	()

Notes:

[47] - AUC not calculated because there was an insufficient number of participants with evaluable data

[48] - AUC not calculated because there was an insufficient number of participants with evaluable data

[49] - AUC not calculated because there was an insufficient number of participants with evaluable data

[50] - AUC not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[51]	0 ^[52]		
Units: ug*h/mL				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	()		
C0D1 - BMS-939429	()	()		
C2D1 - BMS-813160	()	()		
C2D1 - BMS-939429	()	()		

Notes:

[51] - AUC not calculated because there was an insufficient number of participants with evaluable data

[52] - AUC not calculated because there was an insufficient number of participants with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Total Body Clearance (CLT/F)

End point title	Apparent Total Body Clearance (CLT/F)
End point description:	
The total body clearance (CLT/F) is defined as the volume of plasma completely cleared of drug per unit time.	
"99999"=N/A	
End point type	Secondary
End point timeframe:	
From first dose up to prespecified timepoints-C0D1, C2D14	

End point values	Part 1-Arm A- Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A- Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B- Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B- Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	7	4
Units: mL/min				
arithmetic mean (standard deviation)				
C0D14 - BMS-813160	1163.173 (± 588.1385)	744.746 (± 361.5390)	1521.863 (± 1277.8075)	826.468 (± 300.1738)
C2D1 - BMS-813160	956.446 (± 596.7553)	683.958 (± 322.7045)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C- Cohort 1: 2/3L CRC MSS/BMS300BI D + NIVO	Part 1-Arm C- Cohort 2: 2/3L CRC MSS/BMS600Q D + NIVO	Part 1-Arm C- Cohort 3: 2/3L CRC MSS/BMS300Q D + NIVO	Part 1-Arm C- Cohort 4: 2/3L CRC MSS/BMS150Q D + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	3	2
Units: mL/min				
arithmetic mean (standard deviation)				
C0D14 - BMS-813160	1602.009 (± 1123.8919)	961.379 (± 235.4622)	1688.813 (± 1022.7160)	4950.110 (± 781.0155)
C2D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C- Cohort 5: 2L PC/BMS300BI D + NIVO	Part 1-Arm C- Cohort 6: 2L PC/BMS600Q D + NIVO	Part 2-Arm A- Cohort 1a: 2L CRC/BMS300BI D + FOLFIRI	Part 2-Arm A- Cohort 1b: 2L CRC/BMS150Q D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	9	13
Units: mL/min				
arithmetic mean (standard deviation)				
C0D14 - BMS-813160	1135.947 (± 99999)	1032.434 (± 850.2203)	99999 (± 99999)	99999 (± 99999)
C2D1 - BMS-813160	99999 (± 99999)	99999 (± 99999)	1115.087 (± 851.2513)	1813.987 (± 1920.2627)

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BI D + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BI D + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[53]	10	0 ^[54]	0 ^[55]
Units: mL/min				
arithmetic mean (standard deviation)				
C0D14 - BMS-813160	()	99999 (± 99999)	()	()
C2D1 - BMS-813160	()	1440.516 (± 733.5156)	()	()

Notes:

[53] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

[54] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

[55] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BI D + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BI D +		
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		NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[56]	0 ^[57]		
Units: mL/min				
arithmetic mean (standard deviation)				
C0D14 - BMS-813160	()	()		
C2D1 - BMS-813160	()	()		

Notes:

[56] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

[57] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Renal Clearance (CLR)

End point title	Renal Clearance (CLR)
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End point description:

Renal clearance is defined as the rate at which the analytes were removed from the plasma by the kidneys.

End point type	Secondary
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End point timeframe:

From first dose up to prespecified timepoints-C0D1, C0D14

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	4	6	3
Units: mL/min				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	212.411 (± 191.8961)	275.309 (± 277.2659)	139.012 (± 107.2006)	165.327 (± 77.8766)
C0D1 - BMS-939429	74.298 (± 44.8889)	175.109 (± 187.5683)	68.184 (± 52.1580)	77.744 (± 34.8177)
C0D14 - BMS-813160	185.926 (± 56.5866)	124.400 (± 52.1454)	260.786 (± 120.8954)	168.274 (± 72.7581)
C0D14 - BMS-939429	101.042 (± 27.5043)	76.285 (± 30.5071)	145.662 (± 73.3215)	91.490 (± 43.8006)

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	5	4
Units: mL/min				
arithmetic mean (standard deviation)				

COD1 - BMS-813160	155.820 (± 119.3858)	181.930 (± 9.1130)	248.003 (± 82.6974)	236.781 (± 62.8689)
COD1 - BMS-939429	81.027 (± 65.1050)	98.733 (± 6.2562)	140.597 (± 41.7347)	128.943 (± 26.7782)
COD14 - BMS-813160	158.238 (± 82.5905)	194.009 (± 50.1111)	283.842 (± 109.4518)	149.271 (± 72.0204)
COD14 - BMS-939429	87.068 (± 43.9667)	111.649 (± 32.4552)	99999 (± 99999)	99999 (± 99999)

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[58]	1	0 ^[59]	0 ^[60]
Units: mL/min				
arithmetic mean (standard deviation)				
COD1 - BMS-813160	()	99999 (± 99999)	()	()
COD1 - BMS-939429	()	62.007 (± 99999)	()	()
COD14 - BMS-813160	()	115.147 (± 99999)	()	()
COD14 - BMS-939429	()	99999 (± 99999)	()	()

Notes:

[58] - CLR not calculated because there was an insufficient number of participants with evaluable data

[59] - CLR not calculated because there was an insufficient number of participants with evaluable data

[60] - CLR not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[61]	0 ^[62]	0 ^[63]	0 ^[64]
Units: mL/min				
arithmetic mean (standard deviation)				
COD1 - BMS-813160	()	()	()	()
COD1 - BMS-939429	()	()	()	()
COD14 - BMS-813160	()	()	()	()
COD14 - BMS-939429	()	()	()	()

Notes:

[61] - CLR not calculated because there was an insufficient number of participants with evaluable data

[62] - CLR not calculated because there was an insufficient number of participants with evaluable data

[63] - CLR not calculated because there was an insufficient number of participants with evaluable data

[64] - CLR not calculated because there was an insufficient number of participants with evaluable data

End point values	Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[65]	0 ^[66]		
Units: mL/min				
arithmetic mean (standard deviation)				
C0D1 - BMS-813160	()	()		
C0D1 - BMS-939429	()	()		
C0D14 - BMS-813160	()	()		
C0D14 - BMS-939429	()	()		

Notes:

[65] - CLR not calculated because there was an insufficient number of participants with evaluable data

[66] - CLR not calculated because there was an insufficient number of participants with evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who were Anti-Drug Antibody (ADA) Positive

End point title	Number of Participants who were Anti-Drug Antibody (ADA) Positive
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End point description:

The number of participants who are anti-drug antibody positive. ADA-positive participant is a participant with at least 1 ADA-positive sample relative to baseline after initiation of the treatment. ADA-positive sample is in a participant who is baseline ADA negative or with an ADA titer to be at least 4-fold or greater than baseline positive titer.

End point type	Secondary
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End point timeframe:

From first dose up to prespecified timepoints-C1D1, C1D15, C2D1, C3D1, C5D1, C9D1

End point values	Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI	Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI	Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB	Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	10	11
Units: Participants	0	0	0	0

End point values	Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO	Part 1-Arm C-Cohort 2: 2/3L CRC MSS/BMS600QD + NIVO	Part 1-Arm C-Cohort 3: 2/3L CRC MSS/BMS300QD + NIVO	Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	11
Units: Participants	0	0	1	0

End point values	Part 1-Arm C-Cohort 5: 2L PC/BMS300BID	Part 1-Arm C-Cohort 6: 2L PC/BMS600QD	Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID	Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD
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	+ NIVO	+ NIVO	D + FOLFIRI	D + FOLFIRI
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	32	32
Units: Participants	0	0	0	0

End point values	Part 2-Arm A- Cohort 1C: 2L CRC/FOLFIRI	Part 2-Arm B- Cohort 3a: 1L PC/BMS300BID + GEM/NAB	Part 2-Arm B- Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO	Part 2-Arm B- Cohort 3C: 1L PC/GEM/NAB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	35	35	32
Units: Participants	0	0	0	0

End point values	Part 2-Arm C- Cohort 4: 2L PC/BMS300BID + NIVO	Part 2-Arm C- Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	33		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for all-cause mortality from their randomization to study completion, (up to approximately 5.5 years). SAEs and NSAEs were assessed from first dose to 100 days following last dose (up to approximately 3 years).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	P1 1L CRC/BMS300BID + FOLFIRI
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Reporting group description:

First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer

Reporting group title	P1 1L PC/BMS600QD + GEM/NAB
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Reporting group description:

First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE)

Reporting group title	P1 1L PC/BMS300BID + GEM/NAB
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Reporting group description:

First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer

Reporting group title	P1 1L CRC/BMS600QD + FOLFIRI
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Reporting group description:

First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer

Reporting group title	P1 2L PC/BMS300BID + NIVO
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Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

Reporting group title	P1 2/3L CRC MSS/BMS150QD + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Reporting group title	P1 2/3L CRC MSS/BMS300QD + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Reporting group title	P1 2/3L CRC MSS/BMS600QD + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Reporting group title	P1 2/3L CRC MSS/BMS300BID + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Reporting group title	P1 2L PC/BMS600QD + NIVO
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Reporting group description:

Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer

Reporting group title	P2 1L PC/BMS300BID + GEM/NAB + NIVO
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Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer

Reporting group title	P2 1L PC/BMS300BID + GEM/NAB
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Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer

Reporting group title	P2 2L CRC/FOLFIRI
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Reporting group description:

Second-line treatment FOLFIRI in participants with colorectal cancer

Reporting group title	P2 2L CRC/BMS300BID + FOLFIRI
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Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer

Reporting group title	P2 2L CRC/BMS150QD + FOLFIRI
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Reporting group description:

Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer

Reporting group title	P2 1L PC/GEM/NAB
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Reporting group description:

First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer

Reporting group title	P2 2/3L CRC MSS /BMS300BID + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Reporting group title	P2 2L PC/BMS300BID + NIVO
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Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

Reporting group title	P2 2L CRC /FOLFIRI P2 2/3L CRC MSS/BMS300BID + NIVO
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Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

Serious adverse events	P1 1L CRC/BMS300BID + FOLFIRI	P1 1L PC/BMS600QD + GEM/NAB	P1 1L PC/BMS300BID + GEM/NAB
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)	7 / 11 (63.64%)	5 / 10 (50.00%)
number of deaths (all causes)	6	8	8
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytic necrotising lymphadenitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 central nervous system			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Death			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gait disturbance				
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)	
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)	
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Influenza like illness				
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Non-cardiac chest pain				
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Oedema peripheral				
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (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	
Pain				
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Peripheral swelling				
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Pyrexia				

subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Balanoposthitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Streptococcus test positive subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tibia fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Stress cardiomyopathy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 encephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Biliary obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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			
Panniculitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Rash			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19 pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 infective			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis sapovirus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (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
Peritonitis bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Skin infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
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	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P1 1L CRC/BMS600QD + FOLFIRI	P1 2L PC/BMS300BID + NIVO	P1 2/3L CRC MSS/BMS150QD + NIVO
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)	1 / 1 (100.00%)	6 / 11 (54.55%)
number of deaths (all causes)	6	1	7
number of deaths resulting from adverse events	0	1	4

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytic necrotising lymphadenitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	4 / 11 (36.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	1 / 1	4 / 4
Metastases to central nervous system			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatic enzyme increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcus test positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Post procedural complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Panniculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis infective			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis sapovirus			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
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 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P1 2/3L CRC MSS/BMS300QD + NIVO	P1 2/3L CRC MSS/BMS600QD + NIVO	P1 2/3L CRC MSS/BMS300BID + NIVO
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)	6 / 7 (85.71%)	5 / 8 (62.50%)
number of deaths (all causes)	6	6	6
number of deaths resulting from adverse events	5	4	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytic necrotising lymphadenitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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	5 / 7 (71.43%)	3 / 7 (42.86%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 0
deaths causally related to treatment / all	5 / 5	3 / 3	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Deep vein thrombosis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Death			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Balanoposthitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vaginal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcus test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Post procedural bile leak subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 encephalopathy			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 gastrointestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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			
Panniculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 infective			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis sapovirus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
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	P1 2L PC/BMS600QD + NIVO	P2 1L PC/BMS300BID + GEM/NAB + NIVO	P2 1L PC/BMS300BID + GEM/NAB
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	22 / 35 (62.86%)	24 / 35 (68.57%)
number of deaths (all causes)	2	34	33
number of deaths resulting from adverse events	2	4	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytic necrotising lymphadenitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (5.71%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	2 / 2	1 / 1	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (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
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 2 (50.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
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 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	5 / 35 (14.29%)	4 / 35 (11.43%)
occurrences causally related to treatment / all	0 / 0	5 / 10	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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			
Balanoposthitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Prostatic haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	2 / 35 (5.71%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (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
Streptococcus test positive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
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 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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			
Altered state of consciousness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Dizziness			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	3 / 35 (8.57%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 gastrointestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (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
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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			
Panniculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 2	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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 infective			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
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 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis sapovirus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Rectal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	2 / 35 (5.71%)	5 / 35 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
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 / 35 (0.00%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P2 2L CRC/FOLFIRI	P2 2L CRC/BMS300BID + FOLFIRI	P2 2L CRC/BMS150QD + FOLFIRI
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 17 (23.53%)	12 / 32 (37.50%)	12 / 32 (37.50%)
number of deaths (all causes)	10	26	28
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytic necrotising lymphadenitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Balanoposthitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (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
Prostatic haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcus test positive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hip fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (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
Post procedural bile leak			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	0 / 32 (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
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Melaena			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Panniculitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations Appendicitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	1 / 32 (3.13%) 0 / 1 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
Bacteraemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
Biliary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
COVID-19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
Bronchitis viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
COVID-19 pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	1 / 32 (3.13%) 0 / 1 0 / 0
Cholangitis infective subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 17 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0	0 / 32 (0.00%) 0 / 0 0 / 0
Escherichia bacteraemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis sapovirus			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	0 / 32 (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
Peritonitis bacterial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P2 1L PC/GEM/NAB	P2 2/3L CRC MSS /BMS300BID + NIVO	P2 2L PC/BMS300BID + NIVO
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 32 (46.88%)	14 / 24 (58.33%)	17 / 24 (70.83%)
number of deaths (all causes)	26	18	20
number of deaths resulting from adverse events	3	5	8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytic necrotising lymphadenitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			

subjects affected / exposed	1 / 32 (3.13%)	5 / 24 (20.83%)	7 / 24 (29.17%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 7
deaths causally related to treatment / all	1 / 1	5 / 5	7 / 7
Metastases to central nervous system			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Anaphylactic reaction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcus test positive			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

White blood cell count increased subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transfusion reaction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Altered state of consciousness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial mass			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 32 (6.25%)	2 / 24 (8.33%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Abdominal pain lower			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	2 / 24 (8.33%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 32 (3.13%)	2 / 24 (8.33%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Panniculitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Flank pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis infective			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis sapovirus			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 32 (9.38%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P2 2L CRC /FOLFIRI P2 2/3L CRC MSS/BMS300BID + NIVO		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)		
number of deaths (all causes)	7		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Histiocytic necrotising lymphadenitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	1 / 1		
Metastases to central nervous system			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			

Death				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gait disturbance				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 9 (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	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza like illness				
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral swelling				

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 9 (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 distress syndrome			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleuritic pain				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Neutrophil count decreased subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcus test positive subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
White blood cell count increased subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip fracture subjects affected / exposed	0 / 9 (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 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural bile leak subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural complication subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Spinal compression fracture			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transfusion reaction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wrong product administered			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic encephalopathy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial mass			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			

subjects affected / exposed	0 / 9 (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	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal stenosis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant gastrointestinal obstruction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Proctalgia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Portal hypertension			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Panniculitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 9 (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 / 9 (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	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Bronchitis viral				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis infective				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fournier's gangrene				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis sapovirus				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic infection				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella bacteraemia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphangitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis bacterial				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal abscess				

subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal abscess				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	1 / 9 (11.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Splenic infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spontaneous bacterial peritonitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suspected COVID-19				
subjects affected / exposed	0 / 9 (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 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypernatraemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 9 (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	P1 1L CRC/BMS300BID + FOLFIRI	P1 1L PC/BMS600QD + GEM/NAB	P1 1L PC/BMS300BID + GEM/NAB
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	11 / 11 (100.00%)	9 / 10 (90.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	2
Hypotension			
subjects affected / exposed	1 / 10 (10.00%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Lymphorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Venous thrombosis			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 10 (60.00%)	5 / 11 (45.45%)	7 / 10 (70.00%)
occurrences (all)	22	7	9
Cyst			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	5 / 11 (45.45%) 7	1 / 10 (10.00%) 1
Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Mucosal inflammation subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 4	2 / 11 (18.18%) 2	0 / 10 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	2 / 11 (18.18%) 5	1 / 10 (10.00%) 1
Swelling subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Temperature intolerance subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Reproductive system and breast disorders Perineal pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Pelvic pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Atelectasis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	2	2
Dyspnoea exertional			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	2	1	2
Cough			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	2 / 10 (20.00%)
occurrences (all)	0	2	3
Dysphonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hiccups			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Nasal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Pleuritic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Delusion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	3 / 10 (30.00%)
occurrences (all)	0	0	3
Sleep disorder			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	4 / 11 (36.36%)	3 / 10 (30.00%)
occurrences (all)	0	5	6
Amylase increased			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	3 / 10 (30.00%)
occurrences (all)	1	2	5
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	3 / 11 (27.27%)	2 / 10 (20.00%)
occurrences (all)	0	3	4
Blood creatinine increased			
subjects affected / exposed	3 / 10 (30.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	6	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	4 / 10 (40.00%) 7	1 / 11 (9.09%) 2	1 / 10 (10.00%) 2
Lymphocyte count decreased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 4	1 / 11 (9.09%) 1	1 / 10 (10.00%) 4
Weight decreased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 11 (0.00%) 0	3 / 10 (30.00%) 3
Transaminases increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 3	2 / 11 (18.18%) 4	2 / 10 (20.00%) 2
Neutrophil count decreased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	4 / 11 (36.36%) 15	2 / 10 (20.00%) 3
Weight increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	2 / 11 (18.18%) 4	2 / 10 (20.00%) 7
Injury, poisoning and procedural complications			
Fall subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Infusion related reaction			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Post procedural complication			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Stoma site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular access site oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stoma site ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Cardiac dysfunction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0

Nervous system disorders			
Burning sensation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cerebellar infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cholinergic syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	15	1	2
Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	3 / 10 (30.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	14	1	1
Narcolepsy			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	1	1	4
Neuropathy peripheral			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	2	1	2
Paraesthesia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Peripheral motor neuropathy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Polyneuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	4	3	1
Tremor			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 10 (40.00%)	5 / 11 (45.45%)	5 / 10 (50.00%)
occurrences (all)	9	9	6
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Cytopenia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Leukocytosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 10 (20.00%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	3	6	7
Thrombocytopenia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	3	3	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Eye irritation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Photophobia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Photopsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	3 / 11 (27.27%)	4 / 10 (40.00%)
occurrences (all)	1	3	8
Abdominal distension			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Anal haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Anal rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	1	1	0

Constipation			
subjects affected / exposed	3 / 10 (30.00%)	3 / 11 (27.27%)	5 / 10 (50.00%)
occurrences (all)	3	5	7
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Defaecation urgency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	7 / 10 (70.00%)	2 / 11 (18.18%)	3 / 10 (30.00%)
occurrences (all)	18	3	3
Dry mouth			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dyschezia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	0	5	0
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Eructation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	2 / 11 (18.18%) 2	1 / 10 (10.00%) 1
Gingival pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Gingival bleeding subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Haematochezia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Large intestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Intestinal obstruction subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Ileus subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Hypoaesthesia oral subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Lip pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Melaena subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Mouth ulceration subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0

Nausea			
subjects affected / exposed	5 / 10 (50.00%)	7 / 11 (63.64%)	4 / 10 (40.00%)
occurrences (all)	21	8	5
Oesophageal spasm			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	3 / 10 (30.00%)	3 / 11 (27.27%)	4 / 10 (40.00%)
occurrences (all)	3	4	6
Stomatitis			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			

subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Portal hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	3 / 10 (30.00%)	3 / 11 (27.27%)	2 / 10 (20.00%)
occurrences (all)	3	3	2
Dermatitis acneiform			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Hyperhidrosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Nail ridging			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Nail disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Nail discolouration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1

Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 10 (0.00%)	3 / 11 (27.27%)	2 / 10 (20.00%)
occurrences (all)	0	3	6
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	0	2	1
Rash maculo-papular			
subjects affected / exposed	0 / 10 (0.00%)	3 / 11 (27.27%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Rash papular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Skin hyperpigmentation			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Skin discolouration subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1
Rash pruritic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 11 (9.09%) 1	1 / 10 (10.00%) 1
Xeroderma subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Renal and urinary disorders			
Bladder pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Hydronephrosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Proteinuria subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0

Urinary incontinence subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1
Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Endocrine disorders			
Hypothyroidism subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 11 (9.09%) 1	0 / 10 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	1 / 11 (9.09%) 2	1 / 10 (10.00%) 1
Back pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	2 / 11 (18.18%) 2	2 / 10 (20.00%) 4
Bone pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1
Flank pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0
Muscle spasms			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	0	1	2
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	0	1	3
Tendonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	3
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Pneumonia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Rash pustular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pyuria			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	2 / 10 (20.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Decreased appetite			
subjects affected / exposed	3 / 10 (30.00%)	5 / 11 (45.45%)	2 / 10 (20.00%)
occurrences (all)	20	5	2
Hypercalcaemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	2 / 10 (20.00%)
occurrences (all)	1	1	5
Hypocalcaemia			
subjects affected / exposed	1 / 10 (10.00%)	3 / 11 (27.27%)	1 / 10 (10.00%)
occurrences (all)	1	4	2
Hypoalbuminaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 11 (9.09%)	3 / 10 (30.00%)
occurrences (all)	1	1	5
Hyperuricaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	4 / 11 (36.36%)	1 / 10 (10.00%)
occurrences (all)	0	5	1
Hypomagnesaemia			

subjects affected / exposed	3 / 10 (30.00%)	2 / 11 (18.18%)	0 / 10 (0.00%)
occurrences (all)	8	3	0
Hypokalaemia			
subjects affected / exposed	1 / 10 (10.00%)	2 / 11 (18.18%)	1 / 10 (10.00%)
occurrences (all)	1	2	1
Hypovolaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 11 (9.09%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 11 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P1 1L CRC/BMS600QD + FOLFIRI	P1 2L PC/BMS300BID + NIVO	P1 2/3L CRC MSS/BMS150QD + NIVO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	1 / 1 (100.00%)	10 / 11 (90.91%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 8 (50.00%)	0 / 1 (0.00%)	4 / 11 (36.36%)
occurrences (all)	4	0	4
Cyst			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	3 / 11 (27.27%)
occurrences (all)	1	0	3
Swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Hypersensitivity subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Reproductive system and breast disorders			
Perineal pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Aspiration subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Atelectasis subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 1 (100.00%) 1	0 / 11 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Cough			

subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	3	0	1
Dysphonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Nasal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Respiratory tract congestion			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Upper-airway cough syndrome			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Delusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	4 / 8 (50.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0
Sleep disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	2 / 11 (18.18%)
occurrences (all)	3	0	2
Amylase increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	1 / 11 (9.09%)
occurrences (all)	2	1	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	3 / 11 (27.27%)
occurrences (all)	2	0	4
Blood creatinine increased			

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	1 / 11 (9.09%)
occurrences (all)	2	2	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Post procedural complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Vascular access site oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Stoma site ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Vascular access site rash			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac dysfunction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cerebellar infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cholinergic syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Narcolepsy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0

Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	1 / 11 (9.09%) 1
Paraesthesia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Peripheral motor neuropathy subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Restless legs syndrome subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	1 / 11 (9.09%) 1
Polyneuropathy subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 2	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Tremor subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	4 / 8 (50.00%) 4	0 / 1 (0.00%) 0	1 / 11 (9.09%) 1
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Cytopenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Lymphopenia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Photopsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	2 / 11 (18.18%)
occurrences (all)	3	0	3
Abdominal distension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	3 / 11 (27.27%)
occurrences (all)	1	0	3
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Anal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Anal rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	4 / 8 (50.00%)	0 / 1 (0.00%)	3 / 11 (27.27%)
occurrences (all)	5	0	5
Colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	4 / 8 (50.00%)	1 / 1 (100.00%)	3 / 11 (27.27%)
occurrences (all)	5	1	3
Dry mouth			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Dyschezia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Faeces discoloured			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Lip pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	6 / 8 (75.00%)	0 / 1 (0.00%)	2 / 11 (18.18%)
occurrences (all)	6	0	2
Oesophageal spasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Oral dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
Stomatitis			

subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 1 (0.00%) 0	1 / 11 (9.09%) 1
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Portal hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	5 / 8 (62.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	5	0	0
Dermatitis acneiform			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	4	0	0
Dry skin			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nail ridging			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1

Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 2	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Skin discolouration subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Xeroderma subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Renal and urinary disorders			
Bladder pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 11 (0.00%) 0
Hydronephrosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal pain			

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Campylobacter gastroenteritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Enterobacter infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	3	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Gout			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	3	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
Hypovolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P1 2/3L CRC MSS/BMS300QD + NIVO	P1 2/3L CRC MSS/BMS600QD + NIVO	P1 2/3L CRC MSS/BMS300BID + NIVO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	7 / 7 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flushing			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 7 (28.57%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	2	1	1
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lymphorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	3 / 7 (42.86%)	3 / 7 (42.86%)	5 / 8 (62.50%)
occurrences (all)	3	3	5
Cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Swelling subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Temperature intolerance subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders Perineal pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Aspiration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Atelectasis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Dyspnoea			

subjects affected / exposed	3 / 7 (42.86%)	0 / 7 (0.00%)	3 / 8 (37.50%)
occurrences (all)	3	0	3
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 7 (14.29%)	2 / 7 (28.57%)	2 / 8 (25.00%)
occurrences (all)	1	2	2
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Delusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 7 (28.57%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	2	1	1
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0
Injury, poisoning and procedural complications			
Fall subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0
Post procedural complication subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Stoma site pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vascular access site oedema subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Stoma site ulcer subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vascular access site pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	3 / 7 (42.86%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cerebellar infarction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cholinergic syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	2	0	1
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 7 (0.00%)	2 / 7 (28.57%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Narcolepsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	0	1	3
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 7 (42.86%)	4 / 8 (50.00%)
occurrences (all)	2	3	8
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	3 / 7 (42.86%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	4

Anal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Anal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal rash			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 7 (42.86%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	3	1	1
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 7 (42.86%)	1 / 7 (14.29%)	3 / 8 (37.50%)
occurrences (all)	3	2	3
Dry mouth			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Dyschezia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0

Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Faeces discoloured			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lip pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 7 (57.14%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	5	1	2
Oesophageal spasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	5 / 7 (71.43%) 7	1 / 7 (14.29%) 3	1 / 8 (12.50%) 1
Stomatitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Hepatobiliary disorders Hepatic pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Hypertransaminaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Portal hypertension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Alopecia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Dry skin subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Hyperhidrosis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Rash erythematous subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Rash subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Pruritus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	1 / 8 (12.50%) 1
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1
Rash papular subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Skin discolouration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Xeroderma subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Renal and urinary disorders Bladder pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0
Chromaturia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Back pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	2	1	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	2 / 7 (28.57%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)	2 / 7 (28.57%)	4 / 8 (50.00%)
occurrences (all)	2	2	6
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 8 (12.50%)
occurrences (all)	0	1	2
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hypovolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	P1 2L PC/BMS600QD + NIVO	P2 1L PC/BMS300BID + GEM/NAB + NIVO	P2 1L PC/BMS300BID + GEM/NAB
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	34 / 35 (97.14%)	35 / 35 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 35 (8.57%) 3	1 / 35 (2.86%) 1
Embolism subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	2 / 35 (5.71%) 2
Flushing subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	1 / 35 (2.86%) 1
Hypertension subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 35 (8.57%) 4	4 / 35 (11.43%) 6
Hypotension subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 35 (8.57%) 3	4 / 35 (11.43%) 7
Lymphorrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Superficial vein thrombosis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Venous thrombosis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 35 (8.57%) 13	5 / 35 (14.29%) 6
Chest discomfort			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	27 / 35 (77.14%)	23 / 35 (65.71%)
occurrences (all)	1	30	34
Cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	5 / 35 (14.29%)	6 / 35 (17.14%)
occurrences (all)	0	6	9
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	1 / 35 (2.86%)
occurrences (all)	0	2	1
Generalised oedema			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	2	2
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	1 / 2 (50.00%)	12 / 35 (34.29%)	15 / 35 (42.86%)
occurrences (all)	1	12	17
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	2	3
Mucosal inflammation			

subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	1 / 35 (2.86%)
occurrences (all)	0	3	1
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	5 / 35 (14.29%)
occurrences (all)	0	2	5
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	15 / 35 (42.86%)	11 / 35 (31.43%)
occurrences (all)	0	49	24
Swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Breast pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	9 / 35 (25.71%)	10 / 35 (28.57%)
occurrences (all)	0	9	13
Dyspnoea exertional			
subjects affected / exposed	1 / 2 (50.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	1	0	3
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	4 / 35 (11.43%)
occurrences (all)	0	4	5
Cough			
subjects affected / exposed	0 / 2 (0.00%)	11 / 35 (31.43%)	11 / 35 (31.43%)
occurrences (all)	0	13	15
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	2	2
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	3 / 35 (8.57%)
occurrences (all)	0	2	3
Nasal inflammation			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	2 / 35 (5.71%)
occurrences (all)	0	1	2
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences (all)	0	2	1
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	1 / 35 (2.86%)
occurrences (all)	0	3	1
Respiratory tract congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	1 / 35 (2.86%)
occurrences (all)	0	4	1
Sinus congestion			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	1 / 35 (2.86%) 1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	3 / 35 (8.57%)
occurrences (all)	0	3	3
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Delusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	2 / 35 (5.71%)
occurrences (all)	0	4	2
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	4 / 35 (11.43%)
occurrences (all)	0	1	4
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	1 / 35 (2.86%)
occurrences (all)	0	2	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	4 / 35 (11.43%)
occurrences (all)	0	3	5
Alanine aminotransferase increased			

subjects affected / exposed	0 / 2 (0.00%)	10 / 35 (28.57%)	10 / 35 (28.57%)
occurrences (all)	0	16	23
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	3 / 35 (8.57%)
occurrences (all)	0	1	6
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	5 / 35 (14.29%)
occurrences (all)	0	3	7
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	8 / 35 (22.86%)	8 / 35 (22.86%)
occurrences (all)	0	15	19
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	10 / 35 (28.57%)	9 / 35 (25.71%)
occurrences (all)	0	17	13
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	2	4
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	3 / 35 (8.57%)
occurrences (all)	0	3	3
Lipase increased			
subjects affected / exposed	0 / 2 (0.00%)	6 / 35 (17.14%)	3 / 35 (8.57%)
occurrences (all)	0	7	12
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	5 / 35 (14.29%)
occurrences (all)	0	12	13
Weight decreased			

subjects affected / exposed	0 / 2 (0.00%)	9 / 35 (25.71%)	7 / 35 (20.00%)
occurrences (all)	0	9	7
Transaminases increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	3
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	7 / 35 (20.00%)	8 / 35 (22.86%)
occurrences (all)	0	10	23
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	10 / 35 (28.57%)	7 / 35 (20.00%)
occurrences (all)	0	17	12
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	8 / 35 (22.86%)	9 / 35 (25.71%)
occurrences (all)	0	13	13
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	3	3
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Post procedural complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Vascular access site oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Stoma site ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Vascular access site rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Cardiac dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Cerebellar infarction			
subjects affected / exposed	1 / 2 (50.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Cholinergic syndrome			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	5 / 35 (14.29%)	8 / 35 (22.86%)
occurrences (all)	0	6	8
Dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	6 / 35 (17.14%)	9 / 35 (25.71%)
occurrences (all)	0	7	15
Narcolepsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	9 / 35 (25.71%)	4 / 35 (11.43%)
occurrences (all)	0	12	6
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	6 / 35 (17.14%)	6 / 35 (17.14%)
occurrences (all)	0	6	7
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	4 / 35 (11.43%)
occurrences (all)	0	2	6
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	3 / 35 (8.57%)
occurrences (all)	0	0	3
Restless legs syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Polyneuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 2 (0.00%)	11 / 35 (31.43%)	17 / 35 (48.57%)
occurrences (all)	0	12	21
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	3 / 35 (8.57%)
occurrences (all)	0	0	4
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	20 / 35 (57.14%)	21 / 35 (60.00%)
occurrences (all)	0	28	34
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Cytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	6 / 35 (17.14%)
occurrences (all)	0	5	21
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	5 / 35 (14.29%)
occurrences (all)	0	16	20
Iron deficiency anaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	7 / 35 (20.00%)	8 / 35 (22.86%)
occurrences (all)	0	8	17
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	12 / 35 (34.29%)	9 / 35 (25.71%)
occurrences (all)	0	24	26

Eye disorders			
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	3	2
Vitreous floaters			
subjects affected / exposed	1 / 2 (50.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	9 / 35 (25.71%)	13 / 35 (37.14%)
occurrences (all)	0	12	16
Abdominal distension			

subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	3 / 35 (8.57%)
occurrences (all)	0	3	5
Anal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Anal rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	0 / 35 (0.00%)
occurrences (all)	0	3	0
Constipation			
subjects affected / exposed	1 / 2 (50.00%)	15 / 35 (42.86%)	16 / 35 (45.71%)
occurrences (all)	1	21	22
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Defaecation urgency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	0 / 2 (0.00%)	19 / 35 (54.29%)	15 / 35 (42.86%)
occurrences (all)	0	30	29
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	6 / 35 (17.14%)	1 / 35 (2.86%)
occurrences (all)	0	7	1
Dyschezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 2 (50.00%)	3 / 35 (8.57%)	4 / 35 (11.43%)
occurrences (all)	1	4	4
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	1 / 35 (2.86%)
occurrences (all)	0	3	1
Faeces discoloured			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Gingival pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Haematochezia			

subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Large intestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Lip pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	21 / 35 (60.00%)	23 / 35 (65.71%)
occurrences (all)	1	26	34
Oesophageal spasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Proctalgia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	1 / 35 (2.86%)
occurrences (all)	0	2	2
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	11 / 35 (31.43%)	10 / 35 (28.57%)
occurrences (all)	3	14	13
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	7 / 35 (20.00%)	7 / 35 (20.00%)
occurrences (all)	0	8	10
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Portal hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Alopecia			

subjects affected / exposed	0 / 2 (0.00%)	11 / 35 (31.43%)	13 / 35 (37.14%)
occurrences (all)	0	11	16
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	1 / 35 (2.86%)
occurrences (all)	0	3	1
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	4 / 35 (11.43%)
occurrences (all)	0	2	4
Ecchymosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	2	2
Petechiae			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0

Pain of skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	13 / 35 (37.14%)	9 / 35 (25.71%)
occurrences (all)	0	22	9
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	5 / 35 (14.29%)	3 / 35 (8.57%)
occurrences (all)	0	6	3
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	8 / 35 (22.86%)	7 / 35 (20.00%)
occurrences (all)	0	10	11
Rash papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	3 / 35 (8.57%)
occurrences (all)	0	0	3
Skin discolouration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Xeroderma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Chromaturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	3 / 35 (8.57%)
occurrences (all)	0	3	3
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	4 / 35 (11.43%)
occurrences (all)	0	2	4
Proteinuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	5 / 35 (14.29%)	1 / 35 (2.86%)
occurrences (all)	0	5	1
Hyperthyroidism			

subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	6 / 35 (17.14%)	6 / 35 (17.14%)
occurrences (all)	0	6	6
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	8 / 35 (22.86%)
occurrences (all)	0	3	9
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	3 / 35 (8.57%)
occurrences (all)	0	1	4
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	4
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	1 / 35 (2.86%)
occurrences (all)	0	3	1
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	1 / 35 (2.86%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	4 / 35 (11.43%)
occurrences (all)	0	5	7
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			

subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	4 / 35 (11.43%)
occurrences (all)	0	2	5
Tendonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	3 / 35 (8.57%)
occurrences (all)	0	1	3
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	1 / 35 (2.86%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0

Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	3
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	2 / 35 (5.71%)
occurrences (all)	0	1	2
Mucosal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	2 / 35 (5.71%)
occurrences (all)	0	3	2
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	1 / 35 (2.86%)
occurrences (all)	0	2	1
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Rash pustular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Pyuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	3 / 35 (8.57%)	2 / 35 (5.71%)
occurrences (all)	0	3	2

Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 35 (2.86%) 1	0 / 35 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 35 (2.86%) 1	1 / 35 (2.86%) 1
Viral infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Vascular device infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 35 (8.57%) 3	0 / 35 (0.00%) 0
Metabolism and nutrition disorders			
Gout subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 35 (2.86%) 2	1 / 35 (2.86%) 11
Decreased appetite subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	16 / 35 (45.71%) 19	17 / 35 (48.57%) 24
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	2 / 35 (5.71%) 5	0 / 35 (0.00%) 0
Hypernatraemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 35 (0.00%) 0	0 / 35 (0.00%) 0
Hypermagnesaemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	2 / 35 (5.71%) 2	1 / 35 (2.86%) 1
Hyperkalaemia			

subjects affected / exposed	0 / 2 (0.00%)	2 / 35 (5.71%)	2 / 35 (5.71%)
occurrences (all)	0	2	4
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	5 / 35 (14.29%)	9 / 35 (25.71%)
occurrences (all)	0	19	24
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	6 / 35 (17.14%)	6 / 35 (17.14%)
occurrences (all)	0	9	11
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	8 / 35 (22.86%)	10 / 35 (28.57%)
occurrences (all)	0	10	20
Hyperuricaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 35 (2.86%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	2 / 35 (5.71%)
occurrences (all)	0	0	2
Hyperphosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	5 / 35 (14.29%)	5 / 35 (14.29%)
occurrences (all)	0	15	7
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	8 / 35 (22.86%)	5 / 35 (14.29%)
occurrences (all)	0	15	11
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	4 / 35 (11.43%)	4 / 35 (11.43%)
occurrences (all)	0	5	7
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	7 / 35 (20.00%)	6 / 35 (17.14%)
occurrences (all)	0	16	17
Hypovolaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed	0 / 2 (0.00%)	0 / 35 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P2 2L CRC/FOLFIRI	P2 2L CRC/BMS300BID + FOLFIRI	P2 2L CRC/BMS150QD + FOLFIRI
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 17 (94.12%)	32 / 32 (100.00%)	31 / 32 (96.88%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Lymphorrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 17 (17.65%)	4 / 32 (12.50%)	3 / 32 (9.38%)
occurrences (all)	18	19	12
Chest discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	10 / 17 (58.82%)	13 / 32 (40.63%)	11 / 32 (34.38%)
occurrences (all)	12	15	18
Cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 17 (5.88%)	3 / 32 (9.38%)	1 / 32 (3.13%)
occurrences (all)	1	4	1
Chest pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Localised oedema			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Generalised oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	1	1	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	2 / 32 (6.25%)
occurrences (all)	0	3	2
Mucosal inflammation			
subjects affected / exposed	4 / 17 (23.53%)	2 / 32 (6.25%)	5 / 32 (15.63%)
occurrences (all)	4	3	10
Pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	2 / 32 (6.25%)
occurrences (all)	0	2	2
Peripheral swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 17 (5.88%)	5 / 32 (15.63%)	4 / 32 (12.50%)
occurrences (all)	1	5	4
Swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	0 / 32 (0.00%)
occurrences (all)	0	2	0
Reproductive system and breast disorders			
Perineal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			

subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Breast pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	3 / 17 (17.65%)	4 / 32 (12.50%)	7 / 32 (21.88%)
occurrences (all)	3	4	8
Cough			
subjects affected / exposed	1 / 17 (5.88%)	3 / 32 (9.38%)	4 / 32 (12.50%)
occurrences (all)	1	5	4
Dysphonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed	2 / 17 (11.76%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences (all)	2	3	0
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Nasal inflammation			
subjects affected / exposed	2 / 17 (11.76%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	4	1	0
Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	2 / 32 (6.25%)
occurrences (all)	1	1	2
Pleuritic pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	2 / 32 (6.25%)
occurrences (all)	1	2	2
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Sinus congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 17 (5.88%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	1	2	1
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Delusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	0 / 32 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	1 / 17 (5.88%)	4 / 32 (12.50%)	5 / 32 (15.63%)
occurrences (all)	2	4	6
Sleep disorder			

subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	2	1	0
Irritability			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences (all)	0	3	0
Amylase increased			
subjects affected / exposed	1 / 17 (5.88%)	2 / 32 (6.25%)	0 / 32 (0.00%)
occurrences (all)	1	3	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences (all)	0	3	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	4 / 32 (12.50%)
occurrences (all)	0	6	4
Blood creatinine increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	4 / 32 (12.50%) 16	2 / 32 (6.25%) 2
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	3 / 32 (9.38%) 3	2 / 32 (6.25%) 2
Transaminases increased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 32 (3.13%) 1	5 / 32 (15.63%) 6
Neutrophil count decreased subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 21	14 / 32 (43.75%) 17	8 / 32 (25.00%) 18
Weight increased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 17	1 / 32 (3.13%) 1	6 / 32 (18.75%) 15
Injury, poisoning and procedural complications			
Fall subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 32 (3.13%) 1	0 / 32 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 32 (3.13%) 1	0 / 32 (0.00%) 0
Infusion related reaction			

subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	2 / 32 (6.25%)
occurrences (all)	0	2	2
Procedural pain			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Post procedural complication			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vascular access site oedema			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Stoma site ulcer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cardiac dysfunction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	2	0

Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cerebellar infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cholinergic syndrome			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	1 / 17 (5.88%)	3 / 32 (9.38%)	2 / 32 (6.25%)
occurrences (all)	1	3	2
Dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 17 (11.76%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	3	2	1
Narcolepsy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 17 (5.88%)	2 / 32 (6.25%)	3 / 32 (9.38%)
occurrences (all)	1	2	3
Neuropathy peripheral			
subjects affected / exposed	1 / 17 (5.88%)	2 / 32 (6.25%)	3 / 32 (9.38%)
occurrences (all)	1	2	3
Paraesthesia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Peripheral motor neuropathy			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 17 (11.76%)	5 / 32 (15.63%)	0 / 32 (0.00%)
occurrences (all)	2	5	0
Tremor			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 17 (17.65%)	5 / 32 (15.63%)	5 / 32 (15.63%)
occurrences (all)	6	6	6
Febrile neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cytopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0

Leukocytosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	5 / 17 (29.41%)	8 / 32 (25.00%)	9 / 32 (28.13%)
occurrences (all)	12	9	14
Thrombocytopenia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	1	1	5
Eye disorders			
Cataract			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Blepharospasm			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	1	1	0
Dry eye			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 17 (11.76%)	10 / 32 (31.25%)	6 / 32 (18.75%)
occurrences (all)	3	13	7
Abdominal distension			
subjects affected / exposed	1 / 17 (5.88%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences (all)	1	3	0
Abdominal pain lower			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	4 / 32 (12.50%)
occurrences (all)	0	1	5
Anal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Anal rash			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	1

Constipation			
subjects affected / exposed	5 / 17 (29.41%)	13 / 32 (40.63%)	7 / 32 (21.88%)
occurrences (all)	7	15	8
Colitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	9 / 17 (52.94%)	13 / 32 (40.63%)	14 / 32 (43.75%)
occurrences (all)	37	29	24
Dry mouth			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Dyschezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	2 / 17 (11.76%)	2 / 32 (6.25%)	4 / 32 (12.50%)
occurrences (all)	2	3	5
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Faeces discoloured			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	0 / 32 (0.00%)
occurrences (all)	0	2	0
Gingival pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	2 / 32 (6.25%)
occurrences (all)	0	2	2
Large intestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	2
Lip pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1

Nausea			
subjects affected / exposed	8 / 17 (47.06%)	12 / 32 (37.50%)	12 / 32 (37.50%)
occurrences (all)	16	19	17
Oesophageal spasm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	2	0	0
Proctalgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Oral dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	6 / 17 (35.29%)	6 / 32 (18.75%)	10 / 32 (31.25%)
occurrences (all)	12	7	17
Stomatitis			
subjects affected / exposed	4 / 17 (23.53%)	1 / 32 (3.13%)	7 / 32 (21.88%)
occurrences (all)	36	1	10
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			

subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Portal hypertension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	3 / 17 (17.65%)	10 / 32 (31.25%)	7 / 32 (21.88%)
occurrences (all)	3	10	7
Dermatitis acneiform			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	1	1	1
Dry skin			
subjects affected / exposed	2 / 17 (11.76%)	1 / 32 (3.13%)	3 / 32 (9.38%)
occurrences (all)	2	1	3
Hyperhidrosis			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	3 / 32 (9.38%)
occurrences (all)	0	3	4
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Nail disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 17 (11.76%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	2	1	2
Pruritus			
subjects affected / exposed	1 / 17 (5.88%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences (all)	2	3	0
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Rash papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Chromaturia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	2
Hydronephrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0

Urinary incontinence subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Endocrine disorders			
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 32 (3.13%) 1	1 / 32 (3.13%) 1
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	2 / 32 (6.25%) 2	0 / 32 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	4 / 32 (12.50%) 4	5 / 32 (15.63%) 5
Bone pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 32 (3.13%) 1	1 / 32 (3.13%) 1
Flank pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 32 (3.13%) 1	1 / 32 (3.13%) 1
Musculoskeletal pain subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 32 (0.00%) 0	0 / 32 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 32 (0.00%) 0	1 / 32 (3.13%) 1
Muscular weakness subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	2 / 32 (6.25%) 2	0 / 32 (0.00%) 0
Muscle spasms			

subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	0 / 32 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	2 / 17 (11.76%)	5 / 32 (15.63%)	0 / 32 (0.00%)
occurrences (all)	3	5	0
Tendonitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 17 (5.88%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	1	1	0
COVID-19			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	2 / 17 (11.76%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	2	0	0

Cystitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	2	0	0
Diverticulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Nasopharyngitis			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	3 / 32 (9.38%)
occurrences (all)	0	2	4
Mucosal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0

Rash pustular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 17 (5.88%)	3 / 32 (9.38%)	3 / 32 (9.38%)
occurrences (all)	2	3	3
Upper respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	1	2	1
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Vascular device infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	3 / 17 (17.65%)	5 / 32 (15.63%)	2 / 32 (6.25%)
occurrences (all)	3	9	2
Decreased appetite			
subjects affected / exposed	3 / 17 (17.65%)	10 / 32 (31.25%)	6 / 32 (18.75%)
occurrences (all)	5	21	9
Hypercalcaemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 32 (3.13%)	1 / 32 (3.13%)
occurrences (all)	0	1	2
Hyperglycaemia			
subjects affected / exposed	1 / 17 (5.88%)	4 / 32 (12.50%)	0 / 32 (0.00%)
occurrences (all)	2	9	0
Hypocalcaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 32 (6.25%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Hyponatraemia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 32 (9.38%)	0 / 32 (0.00%)
occurrences (all)	0	3	0
Hypomagnesaemia			

subjects affected / exposed	1 / 17 (5.88%)	5 / 32 (15.63%)	0 / 32 (0.00%)
occurrences (all)	1	11	0
Hypokalaemia			
subjects affected / exposed	2 / 17 (11.76%)	5 / 32 (15.63%)	1 / 32 (3.13%)
occurrences (all)	3	8	3
Hypovolaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 17 (5.88%)	0 / 32 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	P2 1L PC/GEM/NAB	P2 2/3L CRC MSS /BMS300BID + NIVO	P2 2L PC/BMS300BID + NIVO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 32 (96.88%)	22 / 24 (91.67%)	19 / 24 (79.17%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Embolism			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	4 / 32 (12.50%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	6	0	0
Hypotension			

subjects affected / exposed	4 / 32 (12.50%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	4	0	1
Lymphorrhoea			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Chest discomfort			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	19 / 32 (59.38%)	8 / 24 (33.33%)	10 / 24 (41.67%)
occurrences (all)	24	9	10
Cyst			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	3 / 32 (9.38%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	3	0	1
Chest pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
Gait disturbance			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	11 / 32 (34.38%)	1 / 24 (4.17%)	2 / 24 (8.33%)
occurrences (all)	11	1	2
Non-cardiac chest pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Mucosal inflammation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences (all)	1	1	2
Peripheral swelling			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	10 / 32 (31.25%)	4 / 24 (16.67%)	5 / 24 (20.83%)
occurrences (all)	13	6	6
Swelling			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Hypersensitivity subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Reproductive system and breast disorders			
Perineal pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Scrotal pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Aspiration subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Atelectasis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	6 / 32 (18.75%) 7	1 / 24 (4.17%) 1	3 / 24 (12.50%) 3
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 24 (4.17%) 1	1 / 24 (4.17%) 3
Epistaxis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Cough			

subjects affected / exposed	3 / 32 (9.38%)	4 / 24 (16.67%)	1 / 24 (4.17%)
occurrences (all)	3	4	1
Dysphonia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Haemoptysis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	3 / 32 (9.38%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
Nasal inflammation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	3 / 32 (9.38%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
Pleuritic pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Pneumonitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Respiratory tract congestion			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Sinus congestion			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 32 (0.00%)	4 / 24 (16.67%)	1 / 24 (4.17%)
occurrences (all)	0	4	1
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Delirium			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Delusion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	3 / 32 (9.38%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
Insomnia			
subjects affected / exposed	1 / 32 (3.13%)	2 / 24 (8.33%)	3 / 24 (12.50%)
occurrences (all)	1	2	3
Sleep disorder			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Alanine aminotransferase increased			
subjects affected / exposed	10 / 32 (31.25%)	2 / 24 (8.33%)	3 / 24 (12.50%)
occurrences (all)	14	2	3
Amylase increased			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	4 / 32 (12.50%)	2 / 24 (8.33%)	5 / 24 (20.83%)
occurrences (all)	7	2	9
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 32 (28.13%)	6 / 24 (25.00%)	3 / 24 (12.50%)
occurrences (all)	18	6	4
Blood alkaline phosphatase increased			
subjects affected / exposed	9 / 32 (28.13%)	5 / 24 (20.83%)	7 / 24 (29.17%)
occurrences (all)	14	5	9
Blood creatinine increased			

subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	3 / 24 (12.50%)
occurrences (all)	1	0	3
Lipase increased			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Lymphocyte count decreased			
subjects affected / exposed	3 / 32 (9.38%)	2 / 24 (8.33%)	4 / 24 (16.67%)
occurrences (all)	5	2	4
Weight decreased			
subjects affected / exposed	5 / 32 (15.63%)	4 / 24 (16.67%)	5 / 24 (20.83%)
occurrences (all)	5	4	5
Transaminases increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	9 / 32 (28.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	14	0	4
Neutrophil count decreased			
subjects affected / exposed	15 / 32 (46.88%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	31	1	0
Weight increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	6 / 32 (18.75%)	2 / 24 (8.33%)	2 / 24 (8.33%)
occurrences (all)	9	2	3
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	3
Procedural pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	3 / 24 (12.50%)
occurrences (all)	1	0	3
Post procedural complication			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular access site oedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Stoma site ulcer			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Cardiac dysfunction			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cerebellar infarction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cholinergic syndrome			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	5 / 32 (15.63%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	5	0	1
Dysaesthesia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	7 / 32 (21.88%)	4 / 24 (16.67%)	0 / 24 (0.00%)
occurrences (all)	7	4	0
Narcolepsy			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 32 (9.38%)	3 / 24 (12.50%)	0 / 24 (0.00%)
occurrences (all)	3	3	0

Neuropathy peripheral subjects affected / exposed occurrences (all)	5 / 32 (15.63%) 5	3 / 24 (12.50%) 3	3 / 24 (12.50%) 4
Paraesthesia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	1 / 24 (4.17%) 1
Peripheral motor neuropathy subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Restless legs syndrome subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Polyneuropathy subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	8 / 32 (25.00%) 8	0 / 24 (0.00%) 0	4 / 24 (16.67%) 4
Tremor subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	1 / 24 (4.17%) 1
Syncope subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	20 / 32 (62.50%) 29	4 / 24 (16.67%) 5	7 / 24 (29.17%) 8
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Cytopenia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Lymphopenia			

subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	5	0	0
Leukopenia			
subjects affected / exposed	4 / 32 (12.50%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	8	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	7 / 32 (21.88%)	2 / 24 (8.33%)	0 / 24 (0.00%)
occurrences (all)	11	2	0
Thrombocytopenia			
subjects affected / exposed	6 / 32 (18.75%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	21	0	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Photopsia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	8 / 32 (25.00%)	6 / 24 (25.00%)	5 / 24 (20.83%)
occurrences (all)	9	7	6
Abdominal distension			
subjects affected / exposed	2 / 32 (6.25%)	1 / 24 (4.17%)	4 / 24 (16.67%)
occurrences (all)	2	1	5
Abdominal pain lower			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	3 / 24 (12.50%)
occurrences (all)	2	0	3
Anal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Anal rash			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	12 / 32 (37.50%)	2 / 24 (8.33%)	4 / 24 (16.67%)
occurrences (all)	15	2	4
Colitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	13 / 32 (40.63%)	7 / 24 (29.17%)	6 / 24 (25.00%)
occurrences (all)	16	12	8
Dry mouth			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Dyschezia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Eructation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 32 (0.00%)	2 / 24 (8.33%)	3 / 24 (12.50%)
occurrences (all)	0	2	3
Faeces discoloured			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Large intestinal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lip pain			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Mouth ulceration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	14 / 32 (43.75%)	5 / 24 (20.83%)	9 / 24 (37.50%)
occurrences (all)	20	6	9
Oesophageal spasm			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	9 / 32 (28.13%)	0 / 24 (0.00%)	5 / 24 (20.83%)
occurrences (all)	11	0	5
Stomatitis			

subjects affected / exposed occurrences (all)	6 / 32 (18.75%) 6	1 / 24 (4.17%) 1	0 / 24 (0.00%) 0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Portal hypertension			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	12 / 32 (37.50%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	12	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 32 (0.00%)	2 / 24 (8.33%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Dry skin			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nail ridging			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	3 / 32 (9.38%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
Pruritus			
subjects affected / exposed	3 / 32 (9.38%)	4 / 24 (16.67%)	0 / 24 (0.00%)
occurrences (all)	3	4	0

Rash maculo-papular subjects affected / exposed occurrences (all)	4 / 32 (12.50%) 4	2 / 24 (8.33%) 2	0 / 24 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 2	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Skin discolouration subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Xeroderma subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Renal and urinary disorders			
Bladder pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 24 (4.17%) 1	0 / 24 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 3	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	1 / 24 (4.17%) 1
Hydronephrosis			

subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Proteinuria subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Urinary tract obstruction subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	1 / 24 (4.17%) 1	0 / 24 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 24 (4.17%) 1	1 / 24 (4.17%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	5 / 32 (15.63%) 5	3 / 24 (12.50%) 3	1 / 24 (4.17%) 1
Back pain subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	2 / 24 (8.33%) 2	2 / 24 (8.33%) 2
Bone pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	0 / 24 (0.00%) 0
Flank pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 24 (0.00%) 0	1 / 24 (4.17%) 1
Musculoskeletal pain			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Muscle spasms			
subjects affected / exposed	2 / 32 (6.25%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	1 / 32 (3.13%)	3 / 24 (12.50%)	0 / 24 (0.00%)
occurrences (all)	1	3	0
Neck pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Pain in extremity			
subjects affected / exposed	2 / 32 (6.25%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	2	2	0
Tendonitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Campylobacter gastroenteritis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Enterobacter infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 32 (6.25%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	2	4	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Gout			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	3 / 32 (9.38%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
Decreased appetite			
subjects affected / exposed	12 / 32 (37.50%)	7 / 24 (29.17%)	7 / 24 (29.17%)
occurrences (all)	14	7	7
Hypercalcaemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	2 / 32 (6.25%)	1 / 24 (4.17%)	2 / 24 (8.33%)
occurrences (all)	2	1	2
Hyperglycaemia			
subjects affected / exposed	5 / 32 (15.63%)	3 / 24 (12.50%)	7 / 24 (29.17%)
occurrences (all)	10	8	11
Hypocalcaemia			
subjects affected / exposed	7 / 32 (21.88%)	1 / 24 (4.17%)	2 / 24 (8.33%)
occurrences (all)	10	1	3
Hypoalbuminaemia			
subjects affected / exposed	6 / 32 (18.75%)	1 / 24 (4.17%)	5 / 24 (20.83%)
occurrences (all)	7	1	5
Hyperuricaemia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Hypoglycaemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 24 (4.17%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			

subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	5 / 32 (15.63%)	1 / 24 (4.17%)	1 / 24 (4.17%)
occurrences (all)	7	1	1
Hyponatraemia			
subjects affected / exposed	7 / 32 (21.88%)	1 / 24 (4.17%)	2 / 24 (8.33%)
occurrences (all)	10	1	3
Hypomagnesaemia			
subjects affected / exposed	4 / 32 (12.50%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences (all)	4	0	2
Hypokalaemia			
subjects affected / exposed	4 / 32 (12.50%)	0 / 24 (0.00%)	2 / 24 (8.33%)
occurrences (all)	8	0	3
Hypovolaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 32 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	P2 2L CRC /FOLFIRI P2 2/3L CRC MSS/BMS300BID + NIVO		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Embolism			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Flushing			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Lymphorrhoea			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Superficial vein thrombosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Venous thrombosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	5 / 9 (55.56%)		
occurrences (all)	8		
Cyst			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Chills			

subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Generalised oedema			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Gait disturbance			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	4		
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pyrexia			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Swelling</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Temperature intolerance</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 9 (22.22%)</p> <p>2</p> <p>1 / 9 (11.11%)</p> <p>1</p> <p>0 / 9 (0.00%)</p> <p>0</p>		
<p>Immune system disorders</p> <p>Hypersensitivity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p>		
<p>Reproductive system and breast disorders</p> <p>Perineal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pelvic pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Breast pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Scrotal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vaginal haemorrhage</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p> <p>0 / 9 (0.00%)</p> <p>0</p> <p>0 / 9 (0.00%)</p> <p>0</p> <p>0 / 9 (0.00%)</p> <p>0</p> <p>0 / 9 (0.00%)</p> <p>0</p>		
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Aspiration</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Atelectasis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dyspnoea</p>	<p>0 / 9 (0.00%)</p> <p>0</p> <p>0 / 9 (0.00%)</p> <p>0</p>		

subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	3		
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	3		
Dysphonia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nasal inflammation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pleuritic pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Productive cough			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Respiratory tract congestion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Respiratory failure			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Sinus congestion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Confusional state			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Delirium			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Delusion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	4 / 9 (44.44%)		
occurrences (all)	5		
Sleep disorder			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Amylase increased			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	3		
Blood bilirubin increased			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	3		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
International normalised ratio increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			

subjects affected / exposed	4 / 9 (44.44%)		
occurrences (all)	4		
Weight increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	3		
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Post procedural complication			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Stoma site pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vascular access site oedema			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Stoma site ulcer			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vascular access site pain			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vascular access site rash			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Cardiac dysfunction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Cerebellar infarction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Cholinergic syndrome			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dizziness			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Narcolepsy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Muscle contractions involuntary			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Restless legs syndrome			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Polyneuropathy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	4 / 9 (44.44%)		
occurrences (all)	4		
Febrile neutropenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Cytopenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Thrombocytopenia			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	4		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Blepharospasm			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dry eye			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Photophobia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Photopsia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vitreous floaters			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	6		
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		

Anal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Abdominal tenderness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Anal inflammation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Anorectal discomfort			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Anal rash			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	3		
Constipation			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	6		
Colitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Defaecation urgency			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	6 / 9 (66.67%)		
occurrences (all)	11		
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dyschezia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Dyspepsia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Dysphagia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Eructation			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Faeces discoloured			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Frequent bowel movements			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Gingival pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Large intestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Intestinal obstruction			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Ileus			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypoaesthesia oral			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Lip pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	5 / 9 (55.56%)		
occurrences (all)	6		
Oesophageal spasm			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Oral pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Proctalgia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Oral dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Oesophagitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Rectal haemorrhage subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1		
Toothache subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1		
Vomiting subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2		
Stomatitis subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1		
Hepatobiliary disorders Hepatic pain subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2		
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Portal hypertension subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Alopecia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1		
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1		
Hyperhidrosis			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nail ridging			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nail disorder			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nail discolouration			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Palmar-plantar erythrodysesthesia syndrome			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Pain of skin			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Onycholysis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Photosensitivity reaction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Rash erythematous subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2		
Pruritus subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Rash maculo-papular subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2		
Rash papular subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Skin discolouration subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Rash pruritic subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Xeroderma subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Renal and urinary disorders Bladder pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0		
Chromaturia			

subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Proteinuria			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Urinary tract obstruction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hyperthyroidism			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Back pain			

subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	4		
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Tendonitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Fungal infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Escherichia bacteraemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Enterobacter infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Paronychia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Rash pustular			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pyuria			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Sepsis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Viral infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vascular device infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	4 / 9 (44.44%)		
occurrences (all)	4		
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypernatraemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypermagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	2		
Hyperglycaemia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			

subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Hyperuricaemia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hyperphosphataemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	2 / 9 (22.22%)		
occurrences (all)	2		
Hypovolaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 May 2017	Original protocol
28 June 2017	Number of patients in each cohort specified in Part 1 and 2. The sample sizes for cohorts in Part 2 are based on the number of evaluable participants needed to support a decision whether or not a treatment is effective using target and historic response rates, while controlling Type 1 error. Clarification in response to FDA feedback. Inclusion criteria to ensure that patients received appropriate prior therapy. Inclusion criteria was modified to ensure that participants received appropriate prior therapy. Grade 4 laboratory abnormalities will be considered DLT. Administration of biologics was updated to acknowledge different local standard of care practices. Safety stopping rules added for Part 2 of the study. List of clinical laboratory assessments updated to align with hepatitis C testing described in exclusion criteria. PBMC sample collections are not needed. Correction of error in Table for Arm A.
11 September 2017	Overall survival is being added as an exploratory endpoint as a direct measure of clinical benefit. In response to health authority feedback, pharmacokinetics (PK) samples will be collected to assess the potential for a drug-drug interaction. A Survival Follow-up period was added to the study design and Schedule of Activities to assess the clinical benefit of study treatments. In response to health authority feedback, PK samples will be collected to assess the potential for a drug-drug interaction. Collection of plasma ctDNA for analysis will enable assessments of tumor mutations, tumor mutation burden, and other biomarkers. Overall survival is being added as an exploratory endpoint as a direct measure of clinical benefit. List of clinical laboratory assessments updated to align with amylase testing described in Nonhepatic Nonhematologic DLT [Section 7.4.1, 3), a), v), (3)] and Guidelines for Permanent Discontinuation in Nivolumab (Arm C) [Section 7.4.7.3, 7), d)].
07 May 2018	-Randomization was added to Part 2 to better evaluate safety and efficacy of the BMS-813160 + chemotherapy combination. A second dose was added to Arm A to test PK, PD, and efficacy of lower dose of BMS-813160 in combination with chemotherapy. - Randomization was added to Part 2 to better evaluate safety and efficacy of BMS-813160 + chemotherapy +/- nivolumab. A combination of BMS-813160 + nivolumab + Gem/nab-paclitaxel combination was added to Arm B to evaluate safety and preliminary efficacy of the combination. - FOLFIRI retreatment and MSI-H post PD-1 cohorts were removed from the study. Bevacizumab can be added to 2L FOLFIRI treatment if appropriate. A staggered dosing (sentinel participant) approach and safety lead in will reduce the number of patients enrolled to the combination if there are any unanticipated toxicities. Study objectives and endpoints were updated to align with revisions to the Part 2 study design. The exploratory BMS-813160 600 mg BID dosing regimen was not initiated in Part 1 of the study, and this regimen will not be explored in Part 2. Eligible participants on the control arms of Arm A and B will be allowed to cross over at the time of PD as they may be eligible for Arm C. Follow-up period extended to monitor for AEs, accounting for the long half-life of nivolumab. Sections were updated to align with revisions in Part 2 of the study design and Section 10.1, Sample Size Determination. Section 2 timing and events tables were updated to align with revisions in Part 2 of the study design. On-going clinical safety update of BMS-813160 in Part 1 provided.

12 July 2018	Table 2-2 and Table 2-7 were added and modified, respectively, to clarify the procedures needed for participants in Part 2 of the study to cross over from Cohorts 1c and 3c to Cohorts 5 and 4, respectively. The study inclusion criteria were reordered to facilitate the transfer of this information in the electronic data capture system (RAVE). An edit check in RAVE will ensure that the site will select the accurate revised new criteria. Table was modified to clarify the biomarker sample collections for cross-over participants. Evolving science indicates that the best collection for the peripheral gene expression profiling analysis is whole blood PAXgene instead of whole blood with isolated PBMC.
12 December 2018	Short Title added for clarity and alignment with Short Title provided on ClinicalTrials.gov. Clarification of the dose and schedule of BMS-813160 in Part 2 of the study. Clarification of the dose and schedule of BMS-813160 in Part 2 of the study. The phrase in bold was added to clarify the dose and schedule of BMS-813160 in Part 2 of the study. Study formulary updated with the addition of 75-mg and 300-mg BMS-813160 tablets. Statement added based on safety data available from Part 1 of the study. Section updated based on preliminary PK data available from Part 1 of the study. Study formulary updated with the addition of 75-mg and 300-mg BMS-813160 tablets. Rationale for the selection of BMS-813160 300 mg BID dosing regimen for primary investigation in Part 2 of the study.
05 December 2019	The following key changes were made: <ul style="list-style-type: none"> - Closed enrollment in Cohort 4 of Part 2. - Removed stratification from the protocol. - Revised time that women of childbearing potential must follow contraception instructions to duration of study therapy plus 10 months.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported