Clinical trial results:
A Phase 3b Open-Label Study to Determine the Long-term Safety and Efficacy of Vedolizumab Subcutaneous in Subjects With Ulcerative Colitis and Crohn's Disease

Summary

EudraCT number	2015-000482-31
Trial protocol	SK CZ NL BG GB DE BE SE DK LT ES HU RO HR IT
Global end of trial date	12 June 2024

Results information

Result version number	v1 (current)
This version publication date	02 April 2025
First version publication date	02 April 2025

Trial information

Trial identification

Sponsor protocol code	MLN0002SC-3030

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02620046
WHO universal trial number (UTN)	U1111-1168-0921

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, United States, MA 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.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	12 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to obtain data on long term safety and tolerability on vedolizumab SC in participants with Ulcerative Colitis (UC) or Crohn's Disease (CD).

Protection of trial subjects:

Each participant signed an informed consent form (ICF) before participating in the study.

Background therapy:

NA

Evidence for comparator: -

Actual start date of recruitment	15 April 2016
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	Australia: 12
Country: Number of subjects enrolled	Czechia: 48
Country: Number of subjects enrolled	Hungary: 30
Country: Number of subjects enrolled	Poland: 157
Country: Number of subjects enrolled	South Africa: 5
Country: Number of subjects enrolled	Romania: 17
Country: Number of subjects enrolled	Serbia: 13
Country: Number of subjects enrolled	Slovakia: 14
Country: Number of subjects enrolled	Japan: 58
Country: Number of subjects enrolled	Korea, Republic of: 22
Country: Number of subjects enrolled	Bosnia and Herzegovina: 3
Country: Number of subjects enrolled	Bulgaria: 5
Country: Number of subjects enrolled	Croatia: 7
Country: Number of subjects enrolled	Estonia: 2
Country: Number of subjects enrolled	Russian Federation: 50
Country: Number of subjects enrolled	Israel: 20
Country: Number of subjects enrolled	Türkiye: 7
Country: Number of subjects enrolled	Ukraine: 47
Country: Number of subjects enrolled	Canada: 34
Country: Number of subjects enrolled	United States: 131
Country: Number of subjects enrolled	Brazil: 13

Country: Number of subjects enrolled	Mexico: 3
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Lithuania: 7
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Sweden: 1
Worldwide total number of subjects	746
EEA total number of subjects	325

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)	705
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites globally from 15 April 2016 to 12 June 2024.

Pre-assignment

Screening details:

Participants who had previously participated in Study MLN0002SC-3027 or MLN0002SC-3031 and were eligible to participate received vedolizumab subcutaneously (SC) [either 108 milligrams (mg) once every two weeks (Q2W) or once per week (QW)] in the disease groups of Ulcerative Colitis and Crohn's Disease in this study. Data is presented accordingly.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ulcerative Colitis: Vedolizumab 108 mg

Arm description:

Participants with UC who completed the Maintenance Phase in MLN0002SC-3027 (Week 52 assessment) or who did not achieve a clinical response
at Week 6 in MLN0002SC-3027 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3027 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab SC
Investigational medicinal product code	MLN0002 SC
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants were administered Vedolizumab SC
once per week (QW) or once every two weeks
(Q2W).

Arm title	Crohn's Disease: Vedolizumab 108 mg

Arm description:

Participants with CD who completed the Maintenance Phase in MLN0002SC-3031 (Week 52 assessment) or who did not achieve a clinical response
at Week 6 in MLN0002SC-3031 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3031 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab SC
Investigational medicinal product code	MLN0002 SC
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants were administered Vedolizumab SC once per week (QW) or once every two weeks (Q2W).

Number of subjects in period 1	Ulcerative Colitis: Vedolizumab 108 mg	Crohn's Disease: Vedolizumab 108 mg
Started	288	458
Completed	125	162
Not completed	163	296
Consent withdrawn by subject	36	66
Adverse event, non-fatal	22	42
Reason Not Specified	13	21
Significant Protocol Deviation	-	1
Pregnancy	3	7
Leukopenia or Lymphopenia	1	-
Lost to follow-up	4	10
Site Termination	3	3
Lack of efficacy	81	146

Baseline characteristics

Reporting groups	
Reporting group title	Ulcerative Colitis: Vedolizumab 108 mg
Reporting group description:	
Participants with UC who completed the Maintenance Phase in MLN0002SC-3027 (Week 52 assessment) or who did not achieve a clinical response at Week 6 in MLN0002SC-3027 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3027 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.	
Reporting group title	Crohn's Disease: Vedolizumab 108 mg
Reporting group description:	
Participants with CD who completed the Maintenance Phase in MLN0002SC-3031 (Week 52 assessment) or who did not achieve a clinical response at Week 6 in MLN0002SC-3031 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3031 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.	

Reporting group values	Ulcerative Colitis: Vedolizumab 108 mg	Crohn's Disease: Vedolizumab 108 mg	Total
Number of subjects	288	458	746
Age Categorical Units: Subjects			
Gender categorical Units: Subjects			
Female	120	214	334
Male	168	244	412
Age categorical Units: Subjects			
<= 18 years	0	0	0
Between 18 and 65	265	440	705
>= 65 years	23	18	41
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	2	4
Asian	58	28	86
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	2	9	11
White	226	417	643
More than one race	0	1	1
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	3	4
Not Hispanic or Latino	34	94	128
Unknown or Not Reported	253	361	614

End points

End points reporting groups

Reporting group title	Ulcerative Colitis: Vedolizumab 108 mg

Reporting group description:

Participants with UC who completed the Maintenance Phase in MLN0002SC-3027 (Week 52 assessment) or who did not achieve a clinical response
at Week 6 in MLN0002SC-3027 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3027 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.

Reporting group title	Crohn's Disease: Vedolizumab 108 mg

Reporting group description:

Participants with CD who completed the Maintenance Phase in MLN0002SC-3031 (Week 52 assessment) or who did not achieve a clinical response
at Week 6 in MLN0002SC-3031 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3031 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.

Subject analysis set title	Ulcerative Colitis: Vedolizumab 108 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with UC who completed the Maintenance Phase in MLN0002SC-3027 (Week 52 assessment) or who did not achieve a clinical response at Week 6 in MLN0002SC-3027 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3027 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.

Subject analysis set title	Crohn's Disease: Vedolizumab 108 mg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants with CD who completed the Maintenance Phase in MLN0002SC-3031 (Week 52 assessment) or who did not achieve a clinical response at Week 6 in MLN0002SC-3031 but who did achieve a clinical response at Week 14 of the parent study after having received a third vedolizumab IV infusion at Week 6 in the parent study received vedolizumab SC 108 mg Q2W in this study whereas participants who withdrew early from the Maintenance Phase (at Week 14 onwards) in MLN0002SC-3031 due to disease worsening or need for rescue medications received vedolizumab SC 108 mg QW.

Primary: Number of Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) Adjusted by Duration of Participant’s Exposure to Long-term Vedolizumab Treatment

End point title	Number of Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) Adjusted by Duration of Participant’s Exposure to Long-term Vedolizumab Treatment[1]

End point description:

Adverse event (AE):any untoward medical occurrence in clinical investigation participant administered drug; it does not necessarily have to have causal relationship with this treatment. AE can therefore be any unfavorable & unintended sign (e.g., clinically significant abnormal laboratory finding), symptom/disease temporally associated with use of drug whether or not it is considered related to drug. TEAE:AE that starts/worsens on or after Study Day 1 (day first dosed in 3030), & no more than 18 weeks/126 days after last dose of study drug. SAEs:serious TEAEs with onset on or after Study Day 1 (defined as day first dosed in 3030), & no more than 18 weeks/126 days after last dose of study drug. Participant years:total exposure-time of participants in respective treatment group. Incidence per 100 participant years:(Number of participants with events*100/participant years). As per planned analysis, data for this endpoint is grouped & presented per disease condition. SAF set.

End point type	Primary

End point timeframe:

Up to 97.9 months

Notes:

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

End point values	Ulcerative Colitis: Vedolizumab 108 mg	Crohn's Disease: Vedolizumab 108 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	288	458		
Units: participants				
TEAEs	231	390		
SAEs	65	121		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Adverse Events of Special Interest (AESIs) Adjusted by Duration of Participant's Exposure to Long-term Vedolizumab Treatment

End point title	Number of Adverse Events of Special Interest (AESIs) Adjusted by Duration of Participant's Exposure to Long-term Vedolizumab Treatment

End point description:

AESIs included hypersensitivity reactions (including injections site reactions), serious infections, malignancies, hepatotoxicity (abnormal liver function test) and progressive multifocal leukoencephalopathy (PML). Participant years is defined as the total exposure-time of the participants in the respective treatment group. Incidence per 100 participant years is defined as (Number of participants with events*100/participant years). As per planned analysis, data for this outcome measure is grouped and presented per disease condition. SAF included all participants who had received at least 1 dose of study medication during this study (MLN0002SC-3030).

End point type	Secondary

End point timeframe:

Up to 97.9 months

End point values	Ulcerative Colitis: Vedolizumab 108 mg	Crohn's Disease: Vedolizumab 108 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	288	458		
Units: events per 100 participant years				
number (not applicable)	16.3	17.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Ulcerative Colitis Achieving Partial Mayo Scoring Clinical Response at Week 48

End point title	Number of Participants with Ulcerative Colitis Achieving Partial Mayo Scoring Clinical Response at Week 48

End point description:

Clinical response is defined as a decrease in the partial Mayo score of at least 2 points and ≥25% from baseline, with an accompanying decrease in rectal bleeding subscore of ≥1 point from baseline or absolute rectal bleeding subscore of ≤1 point. As per planned analysis, data for this outcome measure is grouped and presented for participants with ulcerative colitis. Full Analysis Set (FAS) included all enrolled participants of this study MLN0002SC-3030. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Week 48

End point values	Ulcerative Colitis: Vedolizumab 108 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	288			
Units: participants				
Week 48	168			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Crohn's Disease Achieving Clinical Response Based on Harvey-Bradshaw Index (HBI) Scores at Week 48

End point title	Number of Participants with Crohn's Disease Achieving Clinical Response Based on Harvey-Bradshaw Index (HBI) Scores at Week 48

End point description:

Clinical response is defined as a decrease in HBI score of ≥3 points from baseline in CD participants (randomized early terminator CD participants only [defined as randomized CD participants withdrawn from the parent study between Week 6 and Week 52]). As per planned analysis, data for this outcome measure is grouped and presented for participants with Crohn’s disease. FAS included all enrolled participants of this study MLN0002SC-3030. Subjects analysed is the number of randomised CD participants withdrawn from the parent study between Week 6 and Week 52.

End point type	Secondary

End point timeframe:

Week 48

End point values	Crohn's Disease: Vedolizumab 108 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	114			
Units: participants				
Week 48	32			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Ulcerative Colitis Achieving Clinical Remission Based on Partial Mayo Score

End point title	Number of Participants with Ulcerative Colitis Achieving Clinical Remission Based on Partial Mayo Score

End point description:

Clinical remission is defined as a partial Mayo score of ≤2 with no individual subscore >1. As per planned analysis, data for this outcome measure is grouped and presented for participants with ulcerative colitis. FAS included all enrolled participants of this study MLN0002SC-3030.

End point type	Secondary

End point timeframe:

Week 48

End point values	Ulcerative Colitis: Vedolizumab 108 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	288			
Units: participants				
Week 48	150			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Crohn's Disease Achieving Clinical Remission Based on Harvey-Bradshaw Index (HBI) Scores

End point title	Number of Participants with Crohn's Disease Achieving Clinical Remission Based on Harvey-Bradshaw Index (HBI) Scores

End point description:

Clinical remission is defined as total HBI score of ≤4 points. As per planned analysis, data for this outcome measure is grouped and presented for participants with Crohn’s disease. FAS included all enrolled participants of this study MLN0002SC-3030.

End point type	Secondary

End point timeframe:
Week 48

End point values	Crohn's Disease: Vedolizumab 108 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	458			
Units: participants				
Week 48	217			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 97.9 months

Adverse event reporting additional description:

The SAF included all participants who had received at least 1 dose of study medication in this study (MLN0002SC-3030). Adverse events and All-cause mortality are presented as per the dosing regimen.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Ulcerative Colitis: Only Vedolizumab Q2W

Reporting group description:

Participants with UC who received vedolizumab SC 108 mg Q2W in this study were included in this arm group.

Reporting group title	Ulcerative Colitis: Only Vedolizumab QW

Reporting group description:

Participants with UC who received vedolizumab SC 108 mg QW in this study were included in this arm group.

Reporting group title	Crohn's Disease: Vedolizumab Dose Escalation From Q2W to QW

Reporting group description:

Participants with CD who experienced treatment failure (i.e., disease worsening or need for rescue medications) while receiving vedolizumab 108 mg Q2W during this study and underwent dose escalation to receive vedolizumab SC 108 mg QW were included in this arm group.

Reporting group title	Crohn's Disease: Only Vedolizumab Q2W

Reporting group description:

Participants with CD who received vedolizumab SC 108 mg Q2W in this study were included in this arm group.

Reporting group title	Crohn's Disease: Only Vedolizumab QW

Reporting group description:

Participants with CD who received vedolizumab SC 108 mg QW in this study were included in this arm group.

Reporting group title	Ulcerative Colitis: Vedolizumab Dose Escalation From Q2W to QW

Reporting group description:

Participants with UC who experienced treatment failure (i.e., disease worsening or need for rescue medications) while receiving vedolizumab 108 mg Q2W during this study and underwent dose escalation to receive vedolizumab SC 108 mg QW were included in this arm group.

Serious adverse events	Ulcerative Colitis: Only Vedolizumab Q2W	Ulcerative Colitis: Only Vedolizumab QW	Crohn's Disease: Vedolizumab Dose Escalation From Q2W to QW
Total subjects affected by serious adverse events			
subjects affected / exposed	29 / 163 (17.79%)	12 / 60 (20.00%)	31 / 102 (30.39%)
number of deaths (all causes)	3	0	0
number of deaths resulting from adverse events	3	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenoma			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (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
Colon cancer			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Breast cancer			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 melanoma stage II			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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

Prostate cancer	Additional description: Number of participants at risk in each arm is based on the male population in this study.		
subjects affected / exposed[1]	0 / 102 (0.00%)	0 / 33 (0.00%)	0 / 57 (0.00%)
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 cancer			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Seminoma	Additional description: Number of participants at risk in each arm is based on the male population in this study.		
subjects affected / exposed[2]	0 / 102 (0.00%)	0 / 33 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma	Additional description: Number of participants at risk in each arm is based on the female population in this study.		
subjects affected / exposed[3]	1 / 61 (1.64%)	0 / 27 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papilloma of breast			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
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 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Superficial vein thrombosis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Dysmenorrhoea	Additional description: Number of participants at risk in each arm is based on the female population in this study.		
subjects affected / exposed[4]	0 / 61 (0.00%)	0 / 27 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermenstrual bleeding	Additional description: Number of participants at risk in each arm is based on the female population in this study.		
subjects affected / exposed[5]	0 / 61 (0.00%)	0 / 27 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis	Additional description: Number of participants at risk in each arm is based on the male population in this study.		
subjects affected / exposed[6]	0 / 102 (0.00%)	0 / 33 (0.00%)	0 / 57 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
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	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Hypoxia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Pulmonary embolism			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
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 pneumatocele			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
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			
Hepatic enzyme increased			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrin D dimer increased			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Intestinal anastomosis complication			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 organ contusion			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Procedural pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Meniscus injury			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Liver contusion			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Ligament injury			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Angina pectoris			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Aortic valve stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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			
Presyncope			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 headache			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 163 (1.84%)	1 / 60 (1.67%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Sudden hearing loss			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	14 / 102 (13.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	4 / 163 (2.45%)	7 / 60 (11.67%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 4	1 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 inflammation			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral hernia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (0.00%)
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 toxicity			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal ulcer perforation			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 fibrosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (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
Pancreatitis acute			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (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
Pancreatitis necrotising			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tooth impacted			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			

subjects affected / exposed	0 / 163 (0.00%)	1 / 60 (1.67%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder enlargement			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Onychoclasis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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			
Hydronephrosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis rapidly progressive			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal colic			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Parathyroid disorder			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscular weakness			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 163 (0.61%)	1 / 60 (1.67%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			

subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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	2 / 163 (1.23%)	0 / 60 (0.00%)	0 / 102 (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
Endocarditis staphylococcal			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Cytomegalovirus enteritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	3 / 102 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Rectal abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 bacterial			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (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
Tonsillitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	1 / 102 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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			
Hypoglycaemia			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	0 / 102 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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 / 163 (0.00%)	0 / 60 (0.00%)	0 / 102 (0.00%)
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	Crohn's Disease: Only Vedolizumab Q2W	Crohn's Disease: Only Vedolizumab QW	Ulcerative Colitis: Vedolizumab Dose Escalation From Q2W to QW
Total subjects affected by serious adverse events			
subjects affected / exposed	55 / 239 (23.01%)	35 / 117 (29.91%)	24 / 65 (36.92%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events	2	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Bladder cancer			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenoma			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Colorectal cancer			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip squamous cell carcinoma			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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 melanoma stage II			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Number of participants at risk in each arm is based on the male population in this study.		
subjects affected / exposed[1]	1 / 133 (0.75%)	0 / 54 (0.00%)	0 / 33 (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
Rectal cancer			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seminoma	Additional description: Number of participants at risk in each arm is based on the male population in this study.		
subjects affected / exposed[2]	1 / 133 (0.75%)	0 / 54 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma	Additional description: Number of participants at risk in each arm is based on the female population in this study.		
subjects affected / exposed[3]	0 / 106 (0.00%)	0 / 63 (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
Intraductal papilloma of breast			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial vein thrombosis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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			
Dysmenorrhoea	Additional description: Number of participants at risk in each arm is based on the female population in this study.		
subjects affected / exposed[4]	1 / 106 (0.94%)	0 / 63 (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
Intermenstrual bleeding	Additional description: Number of participants at risk in each arm is based on the female population in this study.		
subjects affected / exposed[5]	1 / 106 (0.94%)	0 / 63 (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
Prostatitis	Additional description: Number of participants at risk in each arm is based on the male population in this study.		
subjects affected / exposed[6]	1 / 133 (0.75%)	0 / 54 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary pneumatocele			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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			
Suicidal ideation			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Fibrin D dimer increased			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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			
Intestinal anastomosis complication			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
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 organ contusion			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Multiple fractures			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 contusion			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 laceration			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Myocardial infarction			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Coronary artery disease			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Ischaemic stroke			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
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 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular headache			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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	3 / 239 (1.26%)	3 / 117 (2.56%)	6 / 65 (9.23%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	2 / 239 (0.84%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Ear and labyrinth disorders			

Sudden hearing loss			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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			
subjects affected / exposed	3 / 239 (1.26%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	2 / 117 (1.71%)	0 / 65 (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
Crohn's disease			
subjects affected / exposed	4 / 239 (1.67%)	10 / 117 (8.55%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 5	1 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	11 / 65 (16.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	2 / 239 (0.84%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Gastrointestinal inflammation			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral hernia			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 toxicity			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal stenosis			
subjects affected / exposed	1 / 239 (0.42%)	2 / 117 (1.71%)	0 / 65 (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
Ileal ulcer perforation			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fibrosis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 stenosis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 necrotising			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Small intestinal obstruction			
subjects affected / exposed	5 / 239 (2.09%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 10	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 stenosis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Subileus			
subjects affected / exposed	0 / 239 (0.00%)	2 / 117 (1.71%)	0 / 65 (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
Tooth impacted			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Gallbladder enlargement			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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			
Onychoclasis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis rapidly progressive			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

IgA nephropathy			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Nephrolithiasis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 239 (0.42%)	1 / 117 (0.85%)	0 / 65 (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
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Parathyroid disorder			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 239 (0.00%)	2 / 117 (1.71%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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 / 239 (0.00%)	0 / 117 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
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 wall abscess			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 239 (0.42%)	1 / 117 (0.85%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	3 / 239 (1.26%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Endocarditis staphylococcal			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus enteritis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
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 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (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
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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 pneumonia			
subjects affected / exposed	4 / 239 (1.67%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (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
Gastroenteritis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Orchitis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.42%)	1 / 117 (0.85%)	0 / 65 (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
Pneumonia bacterial			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	2 / 117 (1.71%)	0 / 65 (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
Respiratory tract infection bacterial			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
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 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Suspected COVID-19			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 117 (0.00%)	0 / 65 (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
Metabolism and nutrition disorders			
Hypoglycaemia			

subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 239 (0.00%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Number of subjects exposed in each arm is based on the male population in this study.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Number of subjects exposed in each arm is based on the male population in this study.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Number of subjects exposed in each arm is based on the female population in this study.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Number of subjects exposed in each arm is based on the female population in this study.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Number of subjects exposed in each arm is based on the female population in this study.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Number of subjects exposed in each arm is based on the male population in this study.

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

Non-serious adverse events	Ulcerative Colitis: Only Vedolizumab Q2W	Ulcerative Colitis: Only Vedolizumab QW	Crohn's Disease: Vedolizumab Dose Escalation From Q2W to QW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	94 / 163 (57.67%)	41 / 60 (68.33%)	90 / 102 (88.24%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	8 / 163 (4.91%)	4 / 60 (6.67%)	5 / 102 (4.90%)
occurrences (all)	12	4	7
Vascular disorders			

Hypertension			
subjects affected / exposed	8 / 163 (4.91%)	0 / 60 (0.00%)	5 / 102 (4.90%)
occurrences (all)	8	0	5
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 163 (4.91%)	3 / 60 (5.00%)	14 / 102 (13.73%)
occurrences (all)	25	4	14
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	1 / 163 (0.61%)	5 / 60 (8.33%)	3 / 102 (2.94%)
occurrences (all)	1	6	3
Anaemia			
subjects affected / exposed	3 / 163 (1.84%)	5 / 60 (8.33%)	6 / 102 (5.88%)
occurrences (all)	8	5	7
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 163 (3.07%)	4 / 60 (6.67%)	10 / 102 (9.80%)
occurrences (all)	5	4	18
Injection site reaction			
subjects affected / exposed	2 / 163 (1.23%)	4 / 60 (6.67%)	0 / 102 (0.00%)
occurrences (all)	21	23	0
Injection site erythema			
subjects affected / exposed	2 / 163 (1.23%)	5 / 60 (8.33%)	1 / 102 (0.98%)
occurrences (all)	7	21	1
Fatigue			
subjects affected / exposed	6 / 163 (3.68%)	0 / 60 (0.00%)	5 / 102 (4.90%)
occurrences (all)	6	0	6
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	2 / 163 (1.23%)	0 / 60 (0.00%)	7 / 102 (6.86%)
occurrences (all)	2	0	8
Abdominal pain			
subjects affected / exposed	8 / 163 (4.91%)	3 / 60 (5.00%)	15 / 102 (14.71%)
occurrences (all)	8	3	21
Anal fistula			

subjects affected / exposed	0 / 163 (0.00%)	0 / 60 (0.00%)	4 / 102 (3.92%)
occurrences (all)	0	0	4
Vomiting			
subjects affected / exposed	4 / 163 (2.45%)	1 / 60 (1.67%)	8 / 102 (7.84%)
occurrences (all)	5	1	10
Crohn's disease			
subjects affected / exposed	1 / 163 (0.61%)	0 / 60 (0.00%)	53 / 102 (51.96%)
occurrences (all)	1	0	106
Diarrhoea			
subjects affected / exposed	12 / 163 (7.36%)	2 / 60 (3.33%)	10 / 102 (9.80%)
occurrences (all)	12	2	16
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 163 (1.84%)	0 / 60 (0.00%)	6 / 102 (5.88%)
occurrences (all)	5	0	6
Nausea			
subjects affected / exposed	7 / 163 (4.29%)	1 / 60 (1.67%)	13 / 102 (12.75%)
occurrences (all)	10	1	17
Colitis ulcerative			
subjects affected / exposed	8 / 163 (4.91%)	14 / 60 (23.33%)	0 / 102 (0.00%)
occurrences (all)	12	15	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 163 (7.36%)	1 / 60 (1.67%)	8 / 102 (7.84%)
occurrences (all)	13	1	8
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	9 / 163 (5.52%)	2 / 60 (3.33%)	9 / 102 (8.82%)
occurrences (all)	10	2	10
Arthralgia			
subjects affected / exposed	8 / 163 (4.91%)	3 / 60 (5.00%)	11 / 102 (10.78%)
occurrences (all)	14	3	13
Infections and infestations			
Bronchitis			
subjects affected / exposed	9 / 163 (5.52%)	1 / 60 (1.67%)	8 / 102 (7.84%)
occurrences (all)	12	1	10
Pneumonia			

subjects affected / exposed	3 / 163 (1.84%)	1 / 60 (1.67%)	2 / 102 (1.96%)
occurrences (all)	3	1	3
Pharyngitis			
subjects affected / exposed	7 / 163 (4.29%)	1 / 60 (1.67%)	3 / 102 (2.94%)
occurrences (all)	7	2	3
Nasopharyngitis			
subjects affected / exposed	23 / 163 (14.11%)	11 / 60 (18.33%)	20 / 102 (19.61%)
occurrences (all)	52	22	31
Influenza			
subjects affected / exposed	4 / 163 (2.45%)	3 / 60 (5.00%)	3 / 102 (2.94%)
occurrences (all)	4	3	3
Herpes zoster			
subjects affected / exposed	4 / 163 (2.45%)	1 / 60 (1.67%)	1 / 102 (0.98%)
occurrences (all)	4	1	1
Gastroenteritis			
subjects affected / exposed	4 / 163 (2.45%)	4 / 60 (6.67%)	4 / 102 (3.92%)
occurrences (all)	7	6	4
COVID-19			
subjects affected / exposed	24 / 163 (14.72%)	2 / 60 (3.33%)	9 / 102 (8.82%)
occurrences (all)	27	2	11
Sinusitis			
subjects affected / exposed	9 / 163 (5.52%)	2 / 60 (3.33%)	8 / 102 (7.84%)
occurrences (all)	12	2	11
Urinary tract infection			
subjects affected / exposed	8 / 163 (4.91%)	2 / 60 (3.33%)	9 / 102 (8.82%)
occurrences (all)	9	2	13
Upper respiratory tract infection			
subjects affected / exposed	28 / 163 (17.18%)	6 / 60 (10.00%)	18 / 102 (17.65%)
occurrences (all)	52	14	31

Non-serious adverse events	Crohn's Disease: Only Vedolizumab Q2W	Crohn's Disease: Only Vedolizumab QW	Ulcerative Colitis: Vedolizumab Dose Escalation From Q2W to QW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	151 / 239 (63.18%)	78 / 117 (66.67%)	55 / 65 (84.62%)
Investigations			

Blood creatine phosphokinase increased			
subjects affected / exposed	13 / 239 (5.44%)	2 / 117 (1.71%)	4 / 65 (6.15%)
occurrences (all)	17	2	4
Vascular disorders			
Hypertension			
subjects affected / exposed	12 / 239 (5.02%)	3 / 117 (2.56%)	4 / 65 (6.15%)
occurrences (all)	15	3	4
Nervous system disorders			
Headache			
subjects affected / exposed	19 / 239 (7.95%)	5 / 117 (4.27%)	7 / 65 (10.77%)
occurrences (all)	34	7	10
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	3 / 239 (1.26%)	1 / 117 (0.85%)	1 / 65 (1.54%)
occurrences (all)	3	1	1
Anaemia			
subjects affected / exposed	14 / 239 (5.86%)	3 / 117 (2.56%)	9 / 65 (13.85%)
occurrences (all)	20	5	9
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	12 / 239 (5.02%)	9 / 117 (7.69%)	3 / 65 (4.62%)
occurrences (all)	13	12	6
Injection site reaction			
subjects affected / exposed	2 / 239 (0.84%)	1 / 117 (0.85%)	0 / 65 (0.00%)
occurrences (all)	2	4	0
Injection site erythema			
subjects affected / exposed	3 / 239 (1.26%)	2 / 117 (1.71%)	1 / 65 (1.54%)
occurrences (all)	5	2	1
Fatigue			
subjects affected / exposed	13 / 239 (5.44%)	5 / 117 (4.27%)	1 / 65 (1.54%)
occurrences (all)	16	5	1
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	10 / 239 (4.18%)	3 / 117 (2.56%)	1 / 65 (1.54%)
occurrences (all)	12	4	1
Abdominal pain			

subjects affected / exposed	33 / 239 (13.81%)	20 / 117 (17.09%)	2 / 65 (3.08%)
occurrences (all)	49	25	2
Anal fistula			
subjects affected / exposed	5 / 239 (2.09%)	7 / 117 (5.98%)	0 / 65 (0.00%)
occurrences (all)	7	8	0
Vomiting			
subjects affected / exposed	13 / 239 (5.44%)	4 / 117 (3.42%)	2 / 65 (3.08%)
occurrences (all)	15	9	2
Crohn's disease			
subjects affected / exposed	26 / 239 (10.88%)	30 / 117 (25.64%)	0 / 65 (0.00%)
occurrences (all)	28	36	0
Diarrhoea			
subjects affected / exposed	18 / 239 (7.53%)	12 / 117 (10.26%)	8 / 65 (12.31%)
occurrences (all)	29	20	9
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 239 (1.26%)	0 / 117 (0.00%)	1 / 65 (1.54%)
occurrences (all)	3	0	1
Nausea			
subjects affected / exposed	14 / 239 (5.86%)	7 / 117 (5.98%)	3 / 65 (4.62%)
occurrences (all)	19	13	3
Colitis ulcerative			
subjects affected / exposed	0 / 239 (0.00%)	0 / 117 (0.00%)	33 / 65 (50.77%)
occurrences (all)	0	0	44
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	10 / 239 (4.18%)	2 / 117 (1.71%)	4 / 65 (6.15%)
occurrences (all)	12	2	5
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	14 / 239 (5.86%)	4 / 117 (3.42%)	3 / 65 (4.62%)
occurrences (all)	16	6	3
Arthralgia			
subjects affected / exposed	34 / 239 (14.23%)	14 / 117 (11.97%)	5 / 65 (7.69%)
occurrences (all)	45	17	9
Infections and infestations			

Bronchitis			
subjects affected / exposed	16 / 239 (6.69%)	8 / 117 (6.84%)	6 / 65 (9.23%)
occurrences (all)	22	9	7
Pneumonia			
subjects affected / exposed	3 / 239 (1.26%)	1 / 117 (0.85%)	4 / 65 (6.15%)
occurrences (all)	3	1	4
Pharyngitis			
subjects affected / exposed	6 / 239 (2.51%)	6 / 117 (5.13%)	4 / 65 (6.15%)
occurrences (all)	6	7	4
Nasopharyngitis			
subjects affected / exposed	26 / 239 (10.88%)	16 / 117 (13.68%)	15 / 65 (23.08%)
occurrences (all)	44	21	26
Influenza			
subjects affected / exposed	12 / 239 (5.02%)	5 / 117 (4.27%)	7 / 65 (10.77%)
occurrences (all)	14	6	7
Herpes zoster			
subjects affected / exposed	2 / 239 (0.84%)	5 / 117 (4.27%)	4 / 65 (6.15%)
occurrences (all)	3	5	4
Gastroenteritis			
subjects affected / exposed	11 / 239 (4.60%)	6 / 117 (5.13%)	2 / 65 (3.08%)
occurrences (all)	14	7	2
COVID-19			
subjects affected / exposed	29 / 239 (12.13%)	4 / 117 (3.42%)	5 / 65 (7.69%)
occurrences (all)	30	4	5
Sinusitis			
subjects affected / exposed	12 / 239 (5.02%)	6 / 117 (5.13%)	4 / 65 (6.15%)
occurrences (all)	19	9	5
Urinary tract infection			
subjects affected / exposed	12 / 239 (5.02%)	5 / 117 (4.27%)	1 / 65 (1.54%)
occurrences (all)	18	7	3
Upper respiratory tract infection			
subjects affected / exposed	38 / 239 (15.90%)	13 / 117 (11.11%)	7 / 65 (10.77%)
occurrences (all)	57	20	13

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 September 2015	The following changes were made as per Amendment 1: 1. Included product complaints section in the study. 2. Updated the clinical pharmacology background and pharmacokinetic (PK) endpoints to reflect dosing simulation modeling.
10 February 2016	The following changes were made as per Amendment 2: 1. Included a benefit-risk assessment in the protocol. 2. Updated the expected treatment duration to a maximum of 5 years. 3. Updated inclusion criterion to clarify colorectal cancer surveillance requirements where enrolled participants were encouraged to undergo surveillance colonoscopies in accordance with local guidelines throughout their participation in the study.
12 May 2016	The following changes were made as per Amendment 3: Added inclusion criterion where participants who had participated in either parent study and, in the opinion of the investigator, tolerated the study drug well could participate in this study.
01 August 2016	The following changes were made as per Amendment 4: 1. Updated schedule of study procedures. 2. Footnotes were updated in the body of the protocol.
08 November 2016	The following changes were made as per Amendment 5: 1. Updated Amendment 4 from non-substantial to substantial.
23 April 2018	The following changes were made as per Amendment 7: 1. Updated the PK analysis text. 2. Updated the antivedolizumab antibodies (AVA) analysis text. 3. Updated the visit window for the QW dosing group from ±1 week to ±3 days. 4. Updated the permitted medications to allow topical steroid treatment for new extraintestinal manifestations (only) of CD after approval by the sponsor.
20 October 2022	The following changes were made as per Amendment 10: Updated the treatment duration to remove the maximum treatment duration of 5 years and to allow treatment to continue until vedolizumab SC was available in the participant's country commercially or through other access programs.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported