Clinical trial results:
A Phase 3, Open-label Study to Determine the Long-term Safety and Efficacy of Vedolizumab (MLN0002) in Subjects with Ulcerative Colitis and Crohn's Disease

Summary

EudraCT number	2008-002784-14
Trial protocol	EE HU AT SK IE LV CZ NL IS PT FR BE ES MT BG SE IT DE GR GB
Global end of trial date	31 October 2017

Results information

Result version number	v1 (current)
This version publication date	09 November 2018
First version publication date	09 November 2018

Trial information

Trial identification

Sponsor protocol code	C13008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00790933
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	One Takeda Parkway, Deerfield, IL, United States, 60015
Public contact	Medical Director, Takeda, +1 8778253327, trialdisclosures@takeda.com
Scientific contact	Medical Director, Takeda, +1 8778253327, 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	31 October 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine the safety profile of long-term vedolizumab treatment

Protection of trial subjects:

At each visit, the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 May 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	4 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Hong Kong: 3
Country: Number of subjects enrolled	India: 63
Country: Number of subjects enrolled	Australia: 100
Country: Number of subjects enrolled	Malaysia: 17
Country: Number of subjects enrolled	New Zealand: 26
Country: Number of subjects enrolled	Singapore: 2
Country: Number of subjects enrolled	South Africa: 36
Country: Number of subjects enrolled	Korea, Republic of: 59
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	Czech Republic: 206
Country: Number of subjects enrolled	Greece: 5
Country: Number of subjects enrolled	Hungary: 98
Country: Number of subjects enrolled	Poland: 82
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	Serbia: 2
Country: Number of subjects enrolled	Slovakia: 31
Country: Number of subjects enrolled	Bulgaria: 11
Country: Number of subjects enrolled	Estonia: 14
Country: Number of subjects enrolled	Israel: 56

Country: Number of subjects enrolled	Latvia: 1
Country: Number of subjects enrolled	Russian Federation: 85
Country: Number of subjects enrolled	Turkey: 9
Country: Number of subjects enrolled	Ukraine: 9
Country: Number of subjects enrolled	Canada: 355
Country: Number of subjects enrolled	United States: 591
Country: Number of subjects enrolled	Austria: 25
Country: Number of subjects enrolled	Belgium: 175
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	France: 46
Country: Number of subjects enrolled	Germany: 44
Country: Number of subjects enrolled	Iceland: 6
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Netherlands: 19
Country: Number of subjects enrolled	Norway: 14
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Sweden: 5
Country: Number of subjects enrolled	Switzerland: 6
Country: Number of subjects enrolled	United Kingdom: 2
Worldwide total number of subjects	2243
EEA total number of subjects	820

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)	2167
From 65 to 84 years	76
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in study at 298 sites in North America, Western/Northern Europe, Central Europe, Eastern Europe, Asia, Australia and Africa from 22 May 2009 to 31 October 2017.

Pre-assignment

Screening details:

Participants with a diagnosis of ulcerative colitis and Crohn's disease who participated in previous studies: C13004 (NCT00619489), C13006 (NCT00783718), C13007 (NCT00783692) and C13011 (NCT01224171) and DeNovo participants were enrolled into 1 treatment group, vedolizumab 300 mg, 30-minute intravenous (IV) infusion, every 4 weeks (Q4W).

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	Vedolizumab 300 mg (C13006)

Arm description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: participants received either vedolizumab matching placebo or vedolizumab every Q4W or vedolizumab every 8 weeks (Q8W), IV infusion up to Week 52.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Intravenous Infusion

Investigational medicinal product name	Vedolizumab Matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Matching Placebo Intravenous Infusion

Arm title	Vedolizumab 300 mg (C13007)

Arm description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: participants received either vedolizumab matching placebo or vedolizumab Q4W or vedolizumab Q8W, IV infusion up to Week 52.

Arm type	Experimental

Investigational medicinal product name	Vedolizumab Matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Matching Placebo Intravenous Infusion

Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Intravenous Infusion

Arm title	Vedolizumab 300 mg (C13011)

Arm description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: participants received either vedolizumab matching placebo or vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab Matching Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Matching Placebo Intravenous Infusion

Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Intravenous Infusion

Arm title	Vedolizumab 300 mg (C13004)

Arm description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 510 weeks including treatment in the previous study. In study C13004: participants received either vedolizumab 2 mg/kg or 6 mg/kg, IV infusion Q8W up to Week 78.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Intravenous Infusion

Arm title	Vedolizumab 300 mg (C13008 De Novo Participants)

Arm description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 260 weeks in participants with Crohn’s disease (CD) or ulcerative colitis (UC) not treated in a previous study.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab Intravenous Infusion

Number of subjects in period 1	Vedolizumab 300 mg (C13006)	Vedolizumab 300 mg (C13007)	Vedolizumab 300 mg (C13011)
Started	675	726	384
Completed	237	246	115
Not completed	438	480	269
Consent withdrawn by subject	123	120	52
Adverse event, non-fatal	94	119	65
Reason Not Specified	8	16	4
Study Terminated by Sponsor	-	-	1
Lost to follow-up	13	31	10
Protocol Violation(s)	8	18	7
Lack of efficacy	192	176	130

Number of subjects in period 1	Vedolizumab 300 mg (C13004)	Vedolizumab 300 mg (C13008 De Novo Participants)
Started	37	421
Completed	23	145
Not completed	14	276
Consent withdrawn by subject	6	50
Adverse event, non-fatal	5	69
Reason Not Specified	1	9
Study Terminated by Sponsor	-	-
Lost to follow-up	1	15
Protocol Violation(s)	-	12
Lack of efficacy	1	121

Baseline characteristics

Reporting groups	
Reporting group title	Vedolizumab 300 mg (C13006)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: participants received either vedolizumab matching placebo or vedolizumab every Q4W or vedolizumab every 8 weeks (Q8W), IV infusion up to Week 52.	
Reporting group title	Vedolizumab 300 mg (C13007)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: participants received either vedolizumab matching placebo or vedolizumab Q4W or vedolizumab Q8W, IV infusion up to Week 52.	
Reporting group title	Vedolizumab 300 mg (C13011)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: participants received either vedolizumab matching placebo or vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.	
Reporting group title	Vedolizumab 300 mg (C13004)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 510 weeks including treatment in the previous study. In study C13004: participants received either vedolizumab 2 mg/kg or 6 mg/kg, IV infusion Q8W up to Week 78.	
Reporting group title	Vedolizumab 300 mg (C13008 De Novo Participants)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 260 weeks in participants with Crohn’s disease (CD) or ulcerative colitis (UC) not treated in a previous study.	

Reporting group values	Vedolizumab 300 mg (C13006)	Vedolizumab 300 mg (C13007)	Vedolizumab 300 mg (C13011)
Number of subjects	675	726	384
Age, Customized Units: Subjects			
<65	646	710	376
>=65	29	16	8
Age Continuous Units: years			
arithmetic mean	41.2	37.3	38.3
standard deviation	± 13.27	± 12.26	± 12.87
Sex: Female, Male Units: Subjects			
Female	280	384	216
Male	395	342	168
Race/Ethnicity, Customized Units: Subjects			
White	557	641	349
Black	10	17	7
Native Hawaiian or Other Pacific Islander	2	0	1
Asian	98	66	14

American Indian or Alaskan Native	2	0	0
Other	6	2	11
Not Reported	0	0	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	29	12	7
Not Hispanic or Latino	631	700	372
Unknown or Not Reported	15	14	5
Region of Enrollment Units: Subjects			
Australia	41	30	8
Hong Kong	1	2	0
India	39	24	0
Malaysia	8	6	3
New Zealand	9	8	1
Singapore	1	1	0
South Africa	13	15	8
Korea, Republic Of	34	18	7
Taiwan, Province Of China	1	3	0
Czech Republic	34	67	36
Greece	5	0	0
Hungary	12	47	22
Poland	53	20	9
Romania	0	4	0
Serbia	0	2	0
Slovakia	0	14	17
Bulgaria	5	6	0
Estonia	9	5	0
Israel	2	12	21
Latvia	0	1	0
Russia	46	24	0
Turkey	6	3	0
Ukraine	0	9	0
Canada	73	98	75
United States	169	166	109
Austria	13	9	3
Belgium	48	48	33
Denmark	2	0	0
France	11	25	10
Germany	10	25	4
Iceland	3	3	0
Ireland	1	1	0
Italy	12	7	4
Netherlands	2	5	12
Norway	7	5	2
Spain	1	4	0
Sweden	0	5	0
Switzerland	2	4	0
United Kingdom	2	0	0

Body Weight			
Units: kg			
arithmetic mean	74.10	71.70	71.29
standard deviation	± 17.934	± 19.600	± 18.951
BMI			
Body Mass Index = weight (kg)/[height (m)^2]. 999999 = BMI was not calculated for de novo participants as height was not collected for these participants. BMI data was available for only 1822 participants.			
Units: kg/m^2			
arithmetic mean	25.39	24.61	24.56
standard deviation	± 5.391	± 6.039	± 5.783

Reporting group values	Vedolizumab 300 mg (C13004)	Vedolizumab 300 mg (C13008 De Novo Participants)	Total
Number of subjects	37	421	2243
Age, Customized			
Units: Subjects			
<65	35	400	2167
>=65	2	21	76
Age Continuous			
Units: years			
arithmetic mean	43.9	39.3	
standard deviation	± 14.24	± 14.23	-
Sex: Female, Male			
Units: Subjects			
Female	20	215	1115
Male	17	206	1128
Race/Ethnicity, Customized			
Units: Subjects			
White	36	398	1981
Black	0	8	42
Native Hawaiian or Other Pacific Islander	0	0	3
Asian	0	9	187
American Indian or Alaskan Native	1	0	3
Other	0	5	24
Not Reported	0	1	3
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	19	67
Not Hispanic or Latino	36	400	2139
Unknown or Not Reported	1	2	37
Region of Enrollment			
Units: Subjects			
Australia	0	21	100
Hong Kong	0	0	3
India	0	0	63
Malaysia	0	0	17
New Zealand	0	8	26
Singapore	0	0	2
South Africa	0	0	36
Korea, Republic Of	0	0	59

Taiwan, Province Of China	0	0	4
Czech Republic	0	69	206
Greece	0	0	5
Hungary	0	17	98
Poland	0	0	82
Romania	0	0	4
Serbia	0	0	2
Slovakia	0	0	31
Bulgaria	0	0	11
Estonia	0	0	14
Israel	0	21	56
Latvia	0	0	1
Russia	15	0	85
Turkey	0	0	9
Ukraine	0	0	9
Canada	22	87	355
United States	0	147	591
Austria	0	0	25
Belgium	0	46	175
Denmark	0	0	2
France	0	0	46
Germany	0	5	44
Iceland	0	0	6
Ireland	0	0	2
Italy	0	0	23
Netherlands	0	0	19
Norway	0	0	14
Spain	0	0	5
Sweden	0	0	5
Switzerland	0	0	6
United Kingdom	0	0	2
Body Weight			
Units: kg			
arithmetic mean	77.66	75.45	
standard deviation	± 18.907	± 18.814	-
BMI			
Body Mass Index = weight (kg)/[height (m)^2]. 999999 = BMI was not calculated for de novo participants as height was not collected for these participants. BMI data was available for only 1822 participants.			
Units: kg/m^2			
arithmetic mean	27.11	999999	
standard deviation	± 6.523	± 999999	-

End points

End points reporting groups

Reporting group title	Vedolizumab 300 mg (C13006)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: participants received either vedolizumab matching placebo or vedolizumab every Q4W or vedolizumab every 8 weeks (Q8W), IV infusion up to Week 52.	
Reporting group title	Vedolizumab 300 mg (C13007)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: participants received either vedolizumab matching placebo or vedolizumab Q4W or vedolizumab Q8W, IV infusion up to Week 52.	
Reporting group title	Vedolizumab 300 mg (C13011)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: participants received either vedolizumab matching placebo or vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.	
Reporting group title	Vedolizumab 300 mg (C13004)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 510 weeks including treatment in the previous study. In study C13004: participants received either vedolizumab 2 mg/kg or 6 mg/kg, IV infusion Q8W up to Week 78.	
Reporting group title	Vedolizumab 300 mg (C13008 De Novo Participants)
Reporting group description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 260 weeks in participants with Crohn’s disease (CD) or ulcerative colitis (UC) not treated in a previous study.	
Subject analysis set title	Vedolizumab 300 mg (UC)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks. Includes De Novo participants and participants previously enrolled in studies C13004 and C13006 with a diagnosis of Ulcerative colitis (UC).	
Subject analysis set title	Vedolizumab 300 mg (CD)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks. Includes De Novo participants and participants previously enrolled in studies C13004, C13007 and C13011 with a diagnosis of Crohn's disease.	
Subject analysis set title	Vedolizumab 300 mg (UC)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks. Includes De Novo participants and participants previously enrolled in studies C13004 and C13006 with a diagnosis of Ulcerative colitis.	
Subject analysis set title	Vedolizumab 300 mg (CD)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks. Includes De Novo participants and participants previously enrolled in studies C13004, C13007 and C13011 with a diagnosis of Crohn's disease.	
Subject analysis set title	Vedolizumab 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300

mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified

criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to

Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified

criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to

Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive

placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)

Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13006 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab matching placebo, IV infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction phase up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, IV infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to

Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately up to 315 weeks including treatment in the previous study. In study C13011: vedolizumab 300 mg, IV infusion, at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab

matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, starting at Week 0, up to approximately 260 weeks in participants with Crohn’s disease not treated in a previous study.

Subject analysis set title	Vedolizumab 300 mg (C13007 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab matching placebo, intravenous infusion at Weeks 0 and 2 (Days 1 and 15). Participants continued to receive placebo during the Maintenance Phase, regardless of treatment response during Induction up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13011 Placebo)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to

approximately 315 weeks including treatment in the previous study. In study C13011: vedolizumab matching placebo, IV infusion at Weeks 0, 2 and 6.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Week 0 and Week 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 50.

Subject analysis set title	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 429 weeks including treatment in the previous study. In study C13007: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase. In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q4W up to Week 52.

Subject analysis set title	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks in participants with ulcerative colitis not treated in previous study.

Subject analysis set title	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W in this study. Treatment duration was up to approximately 430 weeks including treatment in the previous study. In study C13006: vedolizumab 300 mg, intravenous infusion at Weeks 0 and 2 (Days 1 and 15) in Induction Phase.
In the Maintenance Phase, participants who demonstrated a clinical response at Week 6 according to protocol-specified criteria received vedolizumab, IV infusion, Q8W up to Week 50.

Primary: Percentage of Participants with One or More Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Percentage of Participants with One or More Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)[1]

End point description:

An AE is defined as any untoward medical occurrence in clinical investigation participant administered a drug; it does not necessarily have to have causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (eg, clinically significant abnormal laboratory finding)/symptom/disease temporally associated with use of drug, whether or not it is considered related to drug. TEAE is defined as an AE with onset that occurs after receiving study drug. SAE is any experience that suggests significant hazard, contraindication, side effect or precaution that results in death, is life-threatening, required in-patient hospitalization/prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or is medically significant. Safety population, participants who participated in Studies C13004, C13006, C13007, C13011 and De Novo participants who received vedolizumab in Study C13008.

End point type	Primary

End point timeframe:

From first dose of study drug in this study through 16 weeks after the last dose of study drug (Up to approximately 8.5 years)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (UC)	Vedolizumab 300 mg (CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	894	1349		
Units: percentage of participants				
TEAEs	93	96		
SAEs	31	41		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Markedly Abnormal Safety Laboratory Findings

End point title	Number of Participants with Markedly Abnormal Safety Laboratory Findings[2]

End point description:

A laboratory value was considered a marked abnormality if it met the predefined criteria or parameters and the on-treatment value was more extreme than the Baseline value for the following parameters: hemoglobin <= 70 g/L, absolute lymphocyte count <0.5 X 10^9/L, leukocytes <2.0 X 10^9/L (absolute value), platelets <75.0 X 10^9/L, absolute neutrophil Count <1.0 X 10^9/L, prothrombin time >1.25 x upper limit of normal (ULN), alanine aminotransferase (ALT) >3.0 x ULN, aspartate aminotransferase (AST) >3.0 x ULN, bilirubin >2.0 x ULN, amylase >2.0 x ULN, lipase >2.0 x ULN. Safety population, participants who participated in Studies C13004, C13006, C13007, C13011 and De Novo participants who received vedolizumab in Study C13008.

End point type	Primary

End point timeframe:

From first dose of study drug in this study through 16 weeks after the last dose of study drug (Up to 8.5 years)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (UC)	Vedolizumab 300 mg (CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	894	1349		
Units: participants				
Hemoglobin <= 70 g/L	16	11		
Absolute Lymphocyte Count <0.5 X 10^9/L	28	56		
Leukocytes <2.0 X 10^9/L (Absolute Value)	1	3		
Platelets <75.0 X 10^9/L	2	5		
Absolute Neutrophil Count <1.0 X 10^9/L	9	9		
Prothrombin Time >1.25 x ULN	42	37		
ALT >3.0 x ULN	30	47		
AST >3.0 x ULN	35	34		
Bilirubin >2.0 x ULN	12	14		
Amylase >2.0 x ULN	16	36		
Lipase >2.0 x ULN	27	41		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Clinically Significant Mean Change Over Time in Vital Sign Measurements

End point title	Percentage of Participants with Clinically Significant Mean Change Over Time in Vital Sign Measurements[3]

End point description:

Vital signs (heart rate, respiratory rate, systolic and diastolic blood pressure, and temperature) measurements were collected throughout the study. Any clinically significant mean change in vital signs over time as assessed by the investigator was reported as a TEAE. Safety population, participants who participated in Studies C13004, C13006, C13007, C13011 and De Novo participants who received vedolizumab in Study C13008.

End point type	Primary

End point timeframe:

From first dose of study drug in this study through 16 weeks after the last dose of study drug (Up to 8.5 years)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (UC)	Vedolizumab 300 mg (CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	894	1349		
Units: percentage of participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Clinically Significant Electrocardiogram (ECG) Findings

End point title	Number of Participants with Clinically Significant Electrocardiogram (ECG) Findings[4]

End point description:

A standard 12-lead ECG was performed. Any ECGs assessed by the investigator to be clinically significant were reported as TEAEs. Safety population, participants who participated in Studies C13004, C13006, C13007, C13011 and De Novo participants who received vedolizumab in Study C13008.

End point type	Primary

End point timeframe:

From first dose of study drug in this study through 16 weeks after the last dose of study drug (Up to 8.5 years)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (UC)	Vedolizumab 300 mg (CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	894	1349		
Units: participants	7	7		

Statistical analyses

No statistical analyses for this end point

Primary: Time to Major Inflammatory Bowel Disease (IBD) - Related Events

End point title	Time to Major Inflammatory Bowel Disease (IBD) - Related Events[5]

End point description:

IBD-related events included hospitalizations, surgeries, or procedures due to ulcerative colitis and Crohn's disease. Efficacy population included participants who received at least one dose of vedolizumab and had at least one postbaseline disease activity measurement. Here, 9999=Median and Confidence Interval was not estimable due to the low number of participants with events.

End point type	Primary

End point timeframe:

Baseline (Prior to first dose of study drug in C13008) up to end of study (approximately up to 8.5 years)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	2142			
Units: weeks				
median (confidence interval 95%)				
IBD-related events, UC	9999 (9999 to 9999)			
IBD-related events, CD	9999 (9999 to 9999)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 28

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 28[6]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). Total IBDQ score is calculated by summing scores from each domain; Total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. Intent to treat (ITT) population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 28. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 28

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	67	76	52
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	125.34 (± 34.895)	129.12 (± 34.289)	124.37 (± 31.632)	122.33 (± 31.114)
Change at Week 28	60.00 (± 41.165)	62.71 (± 34.600)	62.53 (± 35.072)	57.17 (± 38.851)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	71	127	134
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	127.56 (± 33.718)	127.11 (± 30.537)	123.88 (± 31.620)	124.35 (± 33.310)
Change at Week 28	57.52 (± 42.561)	51.48 (± 34.576)	41.71 (± 36.508)	40.49 (± 39.733)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	161		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	131.44 (± 27.715)	132.14 (± 32.245)		
Change at Week 28	42.90 (± 32.581)	30.84 (± 34.614)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 52

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 52[7]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing the scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 52. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 52

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	65	70	49
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	123.53 (± 36.160)	131.17 (± 33.675)	125.03 (± 32.560)	120.29 (± 30.894)
Change at Week 52	66.84 (± 41.733)	59.89 (± 33.170)	61.06 (± 37.386)	59.31 (± 34.837)

End point values	Vedolizumab 300 mg	Vedolizumab 300 mg	Vedolizumab 300 mg	Vedolizumab 300 mg

	(C13007 Vedolizumab Q8W)	(C13007 Vedolizumab Q4W)	(C13011 Placebo)	(C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	56	63	107	117
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	129.46 (± 34.799)	128.69 (± 30.461)	125.30 (± 30.075)	125.31 (± 34.140)
Change at Week 52	58.87 (± 40.707)	52.30 (± 29.385)	44.31 (± 37.923)	47.38 (± 37.687)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	132	134		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	130.63 (± 28.446)	132.71 (± 33.108)		
Change at Week 52	47.07 (± 30.463)	37.33 (± 40.232)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 76

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 76[8]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing the scores from each domain; the total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 76. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 76

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	63	63	45
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	123.66 (± 36.115)	131.31 (± 33.726)	123.87 (± 31.752)	120.00 (± 29.667)
Change at Week 76	65.53 (± 40.584)	59.88 (± 35.290)	64.27 (± 32.443)	59.91 (± 34.449)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	55	58	91	106
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	128.47 (± 34.724)	129.06 (± 31.694)	124.89 (± 31.629)	125.89 (± 34.478)
Change at Week 76	55.05 (± 47.181)	52.85 (± 36.486)	47.43 (± 35.811)	46.32 (± 36.397)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	118	113		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	130.75 (± 28.587)	132.46 (± 33.245)		
Change at Week 76	50.59 (± 30.794)	40.14 (± 39.305)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 100

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 100[9]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing the scores from each domain; the total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 100. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 100

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	27	58	58
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	120.89 (± 29.745)	124.70 (± 37.614)	130.90 (± 34.361)	124.52 (± 30.033)
Change at Week 100	57.04 (± 38.448)	61.83 (± 41.505)	62.46 (± 32.502)	62.83 (± 34.475)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	55	84	96
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	129.53 (± 35.261)	128.25 (± 32.333)	123.50 (± 29.662)	128.35 (± 33.793)
Change at Week 100	58.53 (± 45.644)	53.40 (± 32.651)	49.89 (± 36.806)	46.95 (± 34.691)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	112	104		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	132.41 (± 28.538)	132.48 (± 32.305)		
Change at Week 100	52.50 (± 32.267)	38.52 (± 36.982)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 124

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 124[10]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing the scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 124. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 124

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	54	43
Units: score on a scale				
arithmetic mean (standard deviation)				

Baseline	127.33 (± 36.470)	130.83 (± 34.399)	123.65 (± 30.180)	119.77 (± 29.963)
Change at Week 124	63.94 (± 44.480)	60.94 (± 37.769)	63.71 (± 34.542)	61.91 (± 36.288)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47	48	80	82
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	132.36 (± 34.573)	130.01 (± 33.454)	122.91 (± 29.869)	129.08 (± 33.576)
Change at Week 124	53.91 (± 44.023)	53.74 (± 34.514)	46.62 (± 38.435)	47.60 (± 40.634)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	95	97		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	132.75 (± 28.131)	131.56 (± 31.567)		
Change at Week 124	54.47 (± 29.636)	40.35 (± 41.543)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 148

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 148[11]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who

were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 148. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 148

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	54	53	41
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	127.33 (± 36.470)	131.95 (± 34.649)	123.02 (± 29.685)	119.07 (± 30.344)
Change at Week 148	60.66 (± 41.786)	62.72 (± 33.786)	65.81 (± 33.232)	60.41 (± 36.074)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	46	76	83
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	132.23 (± 35.877)	130.25 (± 34.108)	122.01 (± 28.967)	128.66 (± 34.624)
Change at Week 148	54.53 (± 48.036)	56.08 (± 32.954)	52.30 (± 39.123)	49.40 (± 36.880)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	93	92		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	133.36 (± 28.616)	132.38 (± 32.172)		
Change at Week 148	54.50 (± 32.874)	42.13 (± 40.030)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 172

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 172[12]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 172. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 172

Notes:

[12] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	24	53	49
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	131.60 (± 36.013)	130.25 (± 36.650)	132.93 (± 34.216)	123.47 (± 30.141)
Change at Week 172	54.91 (± 40.758)	58.67 (± 42.513)	62.20 (± 33.187)	62.16 (± 33.969)

End point values	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	37	43	71	76

Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	120.49 (± 30.221)	132.31 (± 33.860)	120.70 (± 27.535)	127.42 (± 34.779)
Change at Week 172	65.43 (± 35.350)	53.92 (± 33.132)	51.55 (± 40.714)	47.97 (± 35.121)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	89	80		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	133.34 (± 28.981)	131.69 (± 32.229)		
Change at Week 172	56.02 (± 33.863)	41.18 (± 40.805)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 196

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 196[13]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing the scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 196. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 196

Notes:

[13] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	37	50	46
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	127.33 (± 36.470)	119.35 (± 31.651)	135.33 (± 33.596)	122.00 (± 30.129)
Change at Week 196	63.19 (± 38.061)	64.81 (± 36.563)	59.13 (± 33.318)	68.89 (± 34.578)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41	41	66	71
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	130.39 (± 36.410)	132.16 (± 34.217)	121.15 (± 28.703)	126.44 (± 34.826)
Change at Week 196	58.90 (± 46.107)	55.67 (± 32.453)	52.22 (± 42.363)	49.41 (± 35.662)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	51		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	136.55 (± 27.551)	137.27 (± 30.844)		
Change at Week 196	49.05 (± 30.390)	36.35 (± 41.424)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 248

End point title	Change from Baseline in the Inflammatory Bowel Disease

	Questionnaire (IBDQ) Scores at Week 248[14]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 248. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 248

Notes:

[14] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	21	38	36	32
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	116.05 (± 31.747)	133.61 (± 32.538)	120.28 (± 30.875)	116.63 (± 32.888)
Change at Week 248	76.21 (± 38.693)	57.52 (± 31.841)	69.56 (± 38.680)	65.72 (± 34.776)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	31	38	45
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	131.81 (± 35.906)	129.37 (± 31.455)	122.00 (± 27.231)	125.93 (± 35.080)
Change at Week 248	54.97 (± 41.658)	58.76 (± 35.250)	51.39 (± 45.950)	53.04 (± 38.830)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	4		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	127.00 (± 63.930)	128.00 (± 35.749)		
Change at Week 248	73.00 (± 48.446)	72.00 (± 32.156)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 300

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 300[15]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 300. Not applicable (NA) for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 300

Notes:

[15] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	14	13	9
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	100.71 (± 21.831)	137.50 (± 30.478)	120.38 (± 24.401)	119.67 (± 33.463)
Change at Week 300	94.29 (± 38.612)	55.43 (± 41.694)	67.54 (± 27.823)	69.00 (± 41.192)

End point values	Vedolizumab	Vedolizumab	Vedolizumab	Vedolizumab

	300 mg (C13007 Vedolizumab Q8W)	300 mg (C13007 Vedolizumab Q4W)	300 mg (C13011 Placebo)	300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	16	4	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	134.88 (± 36.957)	121.38 (± 30.133)	120.25 (± 19.085)	162.50 (± 47.376)
Change at Week 300	53.00 (± 41.542)	72.00 (± 35.219)	73.50 (± 12.342)	2.00 (± 5.657)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 352

End point title	Change from Baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) Scores at Week 352[16]

End point description:

IBDQ is an instrument used to assess quality of life in adult participants with IBD. It includes 32 questions on 4 domains of Health-Related Quality-of-Life (HRQOL): Bowel Systems (10 items), Emotional Function (12 items), Social Function (5 items), and Systemic Function (5 items). Participants are asked to recall symptoms and quality of life from the last 2 weeks and rate each item on 7-point Likert scale (1=worst to 7=best). A total IBDQ score is calculated by summing scores from each domain; total IBDQ score ranges from 32 to 224, with lower scores reflecting worse HRQOL. A positive change from Baseline indicates improvement. ITT population from studies C13006 and C13007 who received vedolizumab in study C13008. Data is provided for completers in previous studies at both Baseline and Week 352. Data is not available for C13011 Placebo and Vedolizumab arm groups and de novo participants at this time point. Here, 9999=Standard deviation (SD) was not calculated for 1 participant.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 352

Notes:

[16] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	3	1
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	89.00 (± 9999)	120.00 (± 9999)	118.00 (± 32.047)	70.00 (± 9999)
Change at Week 352	123.00 (± 9999)	86.00 (± 9999)	66.00 (± 33.181)	131.00 (± 9999)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	137.00 (± 28.284)	126.00 (± 9999)		
Change at Week 352	37.50 (± 28.991)	84.00 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Scores at Week 28

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Scores at Week 28[17]

End point description:

Short Form-36 (SF-36) is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary(PCS)score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 28. Not applicable for Vedolizumab 300 mg(C13004)arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 28

Notes:

[17] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	67	76	52
Units: score on a scale				
arithmetic mean (standard deviation)				

Baseline	39.57 (± 8.599)	41.15 (± 8.313)	40.05 (± 7.634)	37.05 (± 7.522)
Change at Week 28	10.20 (± 8.792)	8.22 (± 9.015)	8.89 (± 7.110)	9.85 (± 8.789)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	71	127	136
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	37.87 (± 8.113)	39.09 (± 7.771)	37.92 (± 8.355)	36.81 (± 8.274)
Change at Week 28	12.46 (± 8.900)	9.60 (± 7.620)	6.48 (± 8.514)	7.74 (± 9.310)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	151	162		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.06 (± 8.631)	39.20 (± 7.306)		
Change at Week 28	7.07 (± 8.752)	5.67 (± 7.695)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Scores at Week 28

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Scores at Week 28[18]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline

and Week 28. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 28

Notes:

[18] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	67	76	52
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.98 (± 11.349)	40.70 (± 11.226)	38.28 (± 11.039)	35.49 (± 11.139)
Change at Week 28	8.36 (± 13.096)	11.10 (± 11.098)	11.52 (± 12.464)	13.35 (± 11.857)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	71	127	136
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.53 (± 10.631)	37.70 (± 12.423)	36.60 (± 11.545)	38.04 (± 12.567)
Change at Week 28	10.88 (± 12.396)	10.94 (± 12.386)	7.48 (± 12.061)	6.34 (± 13.161)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	151	162		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.87 (± 11.385)	39.29 (± 11.535)		
Change at Week 28	6.48 (± 10.809)	3.72 (± 12.377)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 52

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 52[19]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 52. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 52

Notes:

[19] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	49	56	63
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.94 (± 8.930)	36.75 (± 7.510)	37.82 (± 8.301)	39.23 (± 7.807)
Change at Week 52	9.55 (± 10.155)	9.43 (± 9.088)	12.97 (± 9.147)	9.98 (± 7.824)

End point values	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	107	64	69	118

Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	37.87 (± 7.992)	41.72 (± 8.314)	40.12 (± 7.694)	37.40 (± 8.171)
Change at Week 52	7.48 (± 8.800)	8.57 (± 7.889)	9.77 (± 6.766)	8.97 (± 8.743)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	133	135		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.51 (± 8.454)	39.27 (± 7.469)		
Change at Week 52	8.37 (± 8.401)	6.72 (± 7.842)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 52

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 52[20]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 52. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 52

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	49	56	63
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.33 (± 11.878)	35.43 (± 11.445)	39.45 (± 9.910)	38.98 (± 11.963)
Change at Week 52	10.27 (± 12.895)	12.68 (± 11.843)	10.54 (± 11.719)	8.40 (± 11.598)

End point values	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	107	64	69	118
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	36.80 (± 11.052)	41.18 (± 11.150)	38.29 (± 11.062)	38.54 (± 12.379)
Change at Week 52	8.27 (± 11.770)	10.40 (± 10.777)	12.18 (± 11.506)	7.86 (± 13.129)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	133	135		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.32 (± 11.333)	39.16 (± 11.518)		
Change at Week 52	6.71 (± 10.363)	6.23 (± 12.306)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component at Week 76

End point title	Change from Baseline in Short Form-36 (SF-36) Physical

	Component at Week 76[21]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 76. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 76

Notes:

[21] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	63	63	45
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.79 (± 8.801)	41.33 (± 8.517)	40.07 (± 7.625)	37.03 (± 7.675)
Change at Week 76	9.69 (± 9.714)	8.97 (± 8.891)	10.54 (± 6.416)	10.48 (± 7.797)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13011 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	55	58	106	90
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	37.92 (± 8.353)	39.59 (± 7.809)	37.47 (± 8.147)	37.53 (± 8.286)
Change at Week 76	11.98 (± 9.496)	10.28 (± 7.651)	8.82 (± 8.501)	7.77 (± 8.397)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	120	114		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.73 (± 8.552)	39.25 (± 7.667)		
Change at Week 76	9.73 (± 8.461)	7.31 (± 8.436)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 76

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 76[22]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 76. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 76

Notes:

[22] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	63	63	45
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.41 (± 11.201)	41.30 (± 10.710)	38.26 (± 10.974)	35.50 (± 11.582)
Change at Week 76	9.64 (± 14.272)	8.52 (± 11.462)	10.51 (± 12.334)	12.92 (± 13.174)

End point values	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13011	Vedolizumab 300 mg (C13011

	Vedolizumab Q8W)	Vedolizumab Q4W)	Vedolizumab)	Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	55	58	106	90
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.86 (± 10.046)	38.52 (± 12.244)	39.03 (± 12.679)	36.68 (± 11.947)
Change at Week 76	8.02 (± 14.020)	9.13 (± 13.719)	8.26 (± 12.809)	8.27 (± 12.720)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	120	114		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.32 (± 11.673)	39.16 (± 11.712)		
Change at Week 76	7.77 (± 10.989)	7.16 (± 13.144)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 100

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 100[23]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 100. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 100

Notes:

[23] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	27	58	58
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	36.97 (± 7.677)	41.26 (± 8.825)	41.03 (± 8.260)	40.29 (± 7.480)
Change at Week 100	11.18 (± 8.322)	10.28 (± 8.418)	9.41 (± 7.934)	9.42 (± 7.556)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	84	96	54
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.11 (± 8.169)	37.26 (± 7.974)	37.90 (± 8.297)	39.59 (± 7.989)
Change at Week 100	12.97 (± 9.396)	8.47 (± 8.096)	9.45 (± 8.747)	10.78 (± 8.926)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	114	105		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	41.13 (± 8.579)	39.28 (± 7.458)		
Change at Week 100	9.70 (± 8.869)	7.40 (± 8.473)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 100

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 100[24]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 100. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 100

Notes:

[24] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	27	58	58
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	35.61 (± 11.568)	39.56 (± 11.833)	41.10 (± 11.140)	38.21 (± 10.885)
Change at Week 100	10.64 (± 13.629)	8.80 (± 14.395)	9.87 (± 10.552)	10.82 (± 12.303)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	84	96	54
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.76 (± 10.215)	36.61 (± 11.894)	39.43 (± 12.474)	37.41 (± 11.857)
Change at Week 100	8.94 (± 13.798)	8.25 (± 12.562)	7.93 (± 11.053)	9.98 (± 11.450)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	114	105		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.39 (± 11.559)	39.04 (± 11.604)		
Change at Week 100	7.66 (± 10.685)	6.94 (± 13.189)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Scores at Week 124

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Scores at Week 124[25]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 124. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 124

Notes:

[25] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	54	43
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	41.75 (± 7.947)	41.08 (± 8.219)	39.88 (± 7.332)	37.00 (± 7.854)
Change at Week 124	10.12 (± 9.685)	7.91 (± 9.483)	10.15 (± 8.551)	11.79 (± 8.053)

End point values	Vedolizumab 300 mg	Vedolizumab 300 mg	Vedolizumab 300 mg	Vedolizumab 300 mg

	(C13007 Vedolizumab Q8W)	(C13007 Vedolizumab Q4W)	(C13011 Placebo)	(C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47	48	80	83
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.58 (± 8.078)	39.31 (± 8.279)	37.09 (± 8.044)	38.36 (± 8.240)
Change at Week 124	12.87 (± 8.803)	11.01 (± 8.319)	8.36 (± 7.495)	7.77 (± 9.228)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	97	98		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	41.10 (± 8.747)	39.01 (± 7.363)		
Change at Week 124	10.56 (± 8.804)	9.27 (± 8.274)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Scores at Week 124

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Scores at Week 124[26]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 124. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 124

Notes:

[26] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	54	43
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.34 (± 12.065)	40.81 (± 11.132)	37.85 (± 11.106)	35.29 (± 11.668)
Change at Week 124	9.53 (± 16.289)	10.02 (± 10.734)	9.70 (± 12.781)	11.35 (± 12.681)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47	48	80	83
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.59 (± 9.956)	38.33 (± 12.409)	39.04 (± 12.421)	36.64 (± 11.938)
Change at Week 124	9.20 (± 12.521)	10.38 (± 13.230)	8.50 (± 12.808)	8.78 (± 13.283)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	97	98		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.87 (± 11.156)	38.90 (± 11.427)		
Change at Week 124	7.73 (± 11.048)	6.26 (± 13.274)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 148

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 148[27]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 8 scales, the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 148. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 148

Notes:

[27] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	82	53
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	41.75 (± 7.947)	41.33 (± 8.438)	37.99 (± 8.430)	39.86 (± 7.312)
Change at Week 148	9.08 (± 9.090)	9.35 (± 8.228)	8.94 (± 8.442)	10.34 (± 6.524)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	46	76	40
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.22 (± 7.511)	39.21 (± 8.303)	36.94 (± 8.087)	36.68 (± 8.055)
Change at Week 148	12.54 (± 9.695)	11.26 (± 7.231)	9.37 (± 8.223)	12.15 (± 9.941)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	24		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	43.32 (± 10.405)	38.77 (± 7.024)		
Change at Week 148	9.81 (± 8.727)	10.39 (± 6.824)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 148

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 148[28]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 148. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 148

Notes:

[28] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	82	54	53
Units: score on a scale				
arithmetic mean (standard deviation)				

Baseline	40.34 (± 12.065)	39.36 (± 12.612)	41.20 (± 11.115)	37.48 (± 11.101)
Change at Week 148	6.89 (± 14.522)	8.26 (± 12.835)	9.79 (± 11.176)	11.09 (± 12.299)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	46	76	40
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.56 (± 10.221)	39.21 (± 12.368)	36.71 (± 12.021)	35.05 (± 11.782)
Change at Week 148	9.27 (± 11.720)	9.81 (± 12.524)	8.91 (± 12.680)	10.47 (± 12.517)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	24		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	42.40 (± 8.427)	41.67 (± 10.953)		
Change at Week 148	6.44 (± 12.279)	6.85 (± 12.118)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Scores at Week 172

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Scores at Week 172[29]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were

completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 172. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 172

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	53	49	37
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.82 (± 8.231)	41.52 (± 8.401)	40.23 (± 6.713)	37.29 (± 8.057)
Change at Week 172	13.21 (± 9.194)	9.20 (± 8.324)	9.68 (± 6.804)	11.83 (± 8.042)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	71	25	75
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.16 (± 8.177)	36.92 (± 8.023)	42.23 (± 8.073)	37.85 (± 8.538)
Change at Week 172	10.88 (± 7.837)	9.61 (± 8.461)	10.08 (± 8.996)	9.07 (± 7.519)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	91	81		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	41.12 (± 9.029)	39.30 (± 7.264)		
Change at Week 172	10.47 (± 8.921)	8.55 (± 8.546)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Scores at Week 172

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Scores at Week 172[30]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 172. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 172

Notes:

[30] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	53	49	37
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.77 (± 10.268)	41.49 (± 11.015)	37.00 (± 10.963)	35.47 (± 11.757)
Change at Week 172	9.12 (± 14.244)	10.37 (± 10.420)	9.57 (± 12.850)	12.84 (± 12.281)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	71	25	75

Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.83 (± 12.249)	36.64 (± 11.938)	40.79 (± 12.254)	39.01 (± 12.258)
Change at Week 172	8.45 (± 13.317)	8.78 (± 13.283)	7.43 (± 12.227)	7.52 (± 12.609)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	91	81		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.98 (± 11.479)	38.85 (± 11.972)		
Change at Week 172	8.66 (± 10.767)	7.48 (± 12.329)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 196

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 196[31]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 196. Not applicable for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 196

Notes:

[31] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	33	29	31
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	40.72 (± 7.823)	40.83 (± 8.135)	40.52 (± 7.242)	35.64 (± 7.862)
Change at Week 196	11.82 (± 9.370)	9.98 (± 7.569)	9.31 (± 5.771)	12.35 (± 8.867)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	33	19	21
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	36.65 (± 9.250)	39.33 (± 8.136)	39.53 (± 7.830)	38.40 (± 9.680)
Change at Week 196	14.10 (± 10.616)	11.75 (± 8.261)	6.94 (± 8.667)	9.83 (± 8.111)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 196

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 196[32]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 196. Not applicable for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 196

Notes:

[32] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16	33	29	31
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.46 (± 13.424)	42.74 (± 10.517)	40.40 (± 9.771)	36.17 (± 12.536)
Change at Week 196	9.37 (± 12.087)	9.43 (± 9.349)	9.79 (± 11.516)	12.62 (± 14.386)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	33	19	21
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.07 (± 10.804)	37.63 (± 12.199)	40.11 (± 10.932)	40.05 (± 13.807)
Change at Week 196	10.05 (± 15.471)	9.26 (± 12.732)	8.59 (± 14.645)	9.75 (± 14.824)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 248

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 248[33]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 248. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 248

Notes:

[33] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	21	38	36	32
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.99 (± 7.219)	40.71 (± 7.605)	39.33 (± 6.820)	37.54 (± 8.054)
Change at Week 248	11.22 (± 10.562)	9.95 (± 8.355)	11.43 (± 8.047)	11.70 (± 6.541)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	31	38	45
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.32 (± 8.047)	40.28 (± 8.878)	37.95 (± 8.232)	37.77 (± 8.654)
Change at Week 248	13.88 (± 8.511)	9.98 (± 9.027)	9.32 (± 9.261)	10.50 (± 8.803)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	4		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.17 (± 13.987)	38.79 (± 7.735)		
Change at Week 248	15.98 (± 7.868)	9.88 (± 6.977)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 248

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 248[34]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 248. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 248

Notes:

[34] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	21	38	36	32
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.00 (± 12.537)	41.76 (± 10.579)	38.01 (± 10.876)	34.26 (± 12.252)
Change at Week 248	11.99 (± 13.421)	6.13 (± 9.986)	10.41 (± 13.081)	12.70 (± 12.140)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	31	38	45

Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.06 (± 10.300)	38.04 (± 11.320)	36.41 (± 13.568)	36.77 (± 12.333)
Change at Week 248	9.84 (± 11.433)	10.61 (± 11.204)	7.37 (± 16.473)	10.61 (± 12.188)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	4		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	38.65 (± 18.372)	31.20 (± 4.603)		
Change at Week 248	7.64 (± 18.599)	15.98 (± 13.355)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 300

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 300[35]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (physical functioning, role-physical, bodily pain, general health), the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 300. Not applicable for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 300

Notes:

[35] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	14	13	9
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	36.89 (± 5.913)	38.84 (± 7.720)	39.22 (± 5.469)	36.56 (± 8.514)
Change at Week 300	12.03 (± 10.338)	10.58 (± 8.335)	11.15 (± 6.497)	15.47 (± 9.920)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	16	4	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	34.80 (± 8.431)	39.97 (± 6.626)	41.04 (± 12.016)	34.80 (± 10.515)
Change at Week 300	14.42 (± 6.749)	10.69 (± 6.448)	9.10 (± 9.330)	6.41 (± 9.023)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 300

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 300[36]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary (MCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 300. Not applicable for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 300

Notes:

[36] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	14	13	9
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	34.53 (± 12.530)	43.55 (± 9.074)	35.77 (± 8.585)	33.38 (± 11.168)
Change at Week 300	21.86 (± 13.935)	4.82 (± 10.738)	9.82 (± 11.463)	13.46 (± 15.324)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	16	4	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.40 (± 11.144)	35.79 (± 12.157)	31.35 (± 13.760)	46.99 (± 7.729)
Change at Week 300	6.31 (± 11.916)	14.79 (± 15.281)	19.87 (± 6.588)	-3.67 (± 20.577)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 352

End point title	Change from Baseline in Short Form-36 (SF-36) Physical Component Score at Week 352[37]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. SF-36 includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 8 scales, the physical component summary (PCS) score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006 and C13007 who received vedolizumab in study C13008. Data is provided for completers in previous studies with data available at both Baseline and Week 352. NA for Vedolizumab 300 mg (C13004) arm group. Data is not available for C13011 Placebo and Vedolizumab arm groups and de novo participants at this time point. Here, 9999=SD was not calculated for 1 participant.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 352

Notes:

[37] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	3	1
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	35.68 (± 9999)	38.32 (± 9999)	44.36 (± 0.920)	31.07 (± 9999)
Change at Week 352	17.97 (± 9999)	17.87 (± 9999)	5.06 (± 5.188)	24.06 (± 9999)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	37.14 (± 3.711)	33.67 (± 9999)		
Change at Week 352	11.18 (± 2.116)	18.02 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 352

End point title	Change from Baseline in Short Form-36 (SF-36) Mental Component Score at Week 352[38]

End point description:

SF-36 is a questionnaire that evaluates a person's HRQOL. It includes 36 questions related to 8 health dimensions: physical functioning, role-physical (role limitations due to physical health problems), bodily pain, general health, vitality (energy/fatigue), social functioning, role-emotional (role limitations due to emotional problems), and mental health. Based on these 4 scales (vitality, social functioning, role-emotional, and mental health), the mental component summary(MCS)score is generated which ranges between 0 and 100, with higher scores indicating a better quality of life. A positive change from Baseline indicates improvement. ITT population from studies C13006 and C13007 who received vedolizumab in study C13008. Data is provided for completers in previous studies at both Baseline and Week 352. Data is not available for C13011 Placebo and Vedolizumab arm groups and de novo participants at this time

point. Here, 9999=SD was not calculated for 1 participant.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 352

Notes:

[38] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	3	1
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	42.19 (± 9999)	35.34 (± 9999)	32.72 (± 7.252)	22.18 (± 9999)
Change at Week 352	17.40 (± 9999)	19.87 (± 9999)	14.14 (± 10.114)	25.04 (± 9999)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	39.80 (± 14.563)	42.98 (± 9999)		
Change at Week 352	8.65 (± 7.463)	13.08 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 28

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 28[39]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general health related quality of life (HRQOL) in participants with infectious bowel disease (IBD). It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo

participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 28. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 28

Notes:

[39] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	67	76	52
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.42 (± 1.328)	7.21 (± 1.354)	7.54 (± 1.399)	8.00 (± 1.559)
Change at Week 28	-1.29 (± 1.873)	-1.03 (± 1.705)	-1.44 (± 1.568)	-1.65 (± 1.867)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	71	136	151
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.77 (± 1.442)	7.73 (± 1.434)	7.85 (± 1.525)	7.30 (± 1.360)
Change at Week 28	-1.82 (± 1.675)	-1.46 (± 1.510)	-0.90 (± 1.634)	-0.96 (± 1.380)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - CD)	Vedolizumab 300 mg (C13011 Placebo)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	162	126		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.48 (± 1.420)	7.67 (± 1.475)		
Change at Week 28	-0.69 (± 1.493)	-0.75 (± 1.648)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 28

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 28[40]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 28. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 28

Notes:

[40] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	67	52	62
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	58.4 (± 20.96)	62.1 (± 16.54)	51.5 (± 17.57)	52.2 (± 18.72)
Change at Week 28	22.7 (± 24.11)	20.0 (± 18.75)	23.8 (± 23.79)	27.6 (± 22.58)

End point values	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	75	70	125	135
Units: score on a scale				

arithmetic mean (standard deviation)				
Baseline	53.5 (± 17.30)	52.3 (± 18.39)	53.2 (± 18.02)	51.3 (± 19.09)
Change at Week 28	25.1 (± 22.09)	23.7 (± 22.51)	16.8 (± 22.55)	19.9 (± 22.44)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	157		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	56.4 (± 19.64)	55.6 (± 16.72)		
Change at Week 28	17.1 (± 21.75)	13.4 (± 19.48)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 52

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 52[41]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 52. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 52

Notes:

[41] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	65	70	56
Units: score on a scale				

arithmetic mean (standard deviation)				
Baseline	7.50 (± 1.368)	7.17 (± 1.318)	7.54 (± 1.390)	7.75 (± 1.468)
Change at Week 52	-1.59 (± 1.775)	-1.00 (± 1.571)	-1.43 (± 1.556)	-1.77 (± 1.640)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	63	107	118	133
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.65 (± 1.358)	7.62 (± 1.398)	7.74 (± 1.538)	7.33 (± 1.386)
Change at Week 52	-1.46 (± 1.457)	-0.87 (± 1.666)	-1.15 (± 1.703)	-0.95 (± 1.551)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - CD)	Vedolizumab 300 mg (C13007 Placebo)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	135	48		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.49 (± 1.429)	8.08 (± 1.499)		
Change at Week 52	-0.85 (± 1.637)	-1.60 (± 1.673)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 52

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 52[42]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in

previous studies and de novo participants for whom data was collected at both Baseline and Week 52. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 52

Notes:

[42] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	65	70	49	56
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	61.9 (± 16.18)	52.3 (± 18.09)	50.8 (± 17.82)	52.6 (± 19.43)
Change at Week 52	18.5 (± 20.31)	27.0 (± 21.87)	27.9 (± 20.70)	30.8 (± 21.59)

End point values	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	118	31	62	105
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	52.2 (± 18.94)	57.5 (± 21.39)	52.7 (± 18.38)	53.3 (± 17.21)
Change at Week 52	23.5 (± 23.03)	22.9 (± 27.46)	25.0 (± 18.85)	19.9 (± 22.83)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	129	133		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	55.9 (± 20.51)	56.3 (± 16.21)		
Change at Week 52	20.8 (± 21.93)	17.6 (± 22.69)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 76

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 76[43]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 76. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 76

Notes:

[43] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	63	45	58
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.48 (± 1.379)	7.56 (± 1.267)	8.11 (± 1.434)	7.64 (± 1.385)
Change at Week 76	-1.38 (± 1.498)	-1.33 (± 1.513)	-1.67 (± 1.430)	-1.52 (± 1.466)

End point values	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	106	113	120	62
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.74 (± 1.545)	7.52 (± 1.464)	7.28 (± 1.348)	7.18 (± 1.337)
Change at Week 76	-1.14 (± 1.496)	-1.05 (± 1.546)	-1.26 (± 1.481)	-1.05 (± 1.583)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13011 Placebo)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54	89		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.72 (± 1.420)	7.69 (± 1.489)		
Change at Week 76	-1.50 (± 1.724)	-1.11 (± 1.518)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 76

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 76[44]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 76. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 76

Notes:

[44] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	63	106	113
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	58.8 (± 21.93)	52.0 (± 18.47)	51.4 (± 18.99)	55.8 (± 16.19)

Change at Week 76	20.9 (± 25.66)	25.1 (± 19.62)	23.3 (± 21.40)	17.8 (± 22.04)

End point values	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	62	54	44	57
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	62.3 (± 17.01)	52.0 (± 19.38)	50.7 (± 16.81)	52.4 (± 18.88)
Change at Week 76	18.7 (± 20.65)	30.3 (± 23.68)	27.3 (± 18.87)	27.0 (± 21.49)

End point values	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	88	119		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	52.5 (± 17.18)	56.1 (± 20.36)		
Change at Week 76	22.2 (± 20.82)	19.2 (± 25.10)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 100

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 100[45]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 100. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 100

Notes:

[45] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	27	58	58
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	8.04 (± 1.507)	7.48 (± 1.451)	7.22 (± 1.325)	7.55 (± 1.391)
Change at Week 100	-1.64 (± 1.773)	-1.48 (± 1.602)	-1.26 (± 1.528)	-1.43 (± 1.452)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	49	55	84	96
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.69 (± 1.446)	7.67 (± 1.375)	7.71 (± 1.428)	7.71 (± 1.507)
Change at Week 100	-1.73 (± 1.741)	-1.62 (± 1.394)	-1.04 (± 1.609)	-1.16 (± 1.538)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	114	105		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.28 (± 1.360)	7.53 (± 1.401)		
Change at Week 100	-1.37 (± 1.477)	-0.98 (± 1.473)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 100

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 100[46]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 100. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 100

Notes:

[46] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	58	49
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	59.2 (± 22.81)	61.3 (± 16.80)	52.9 (± 16.94)	53.8 (± 18.76)
Change at Week 100	20.4 (± 27.47)	20.7 (± 17.45)	26.4 (± 21.82)	29.4 (± 23.09)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13011 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	112	54	44	82
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	56.5 (± 20.68)	51.9 (± 19.02)	50.7 (± 16.81)	51.9 (± 16.53)
Change at Week 100	19.4 (± 26.78)	26.9 (± 21.76)	26.9 (± 22.39)	22.3 (± 20.11)

End point values	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo		

		Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	95	103		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	52.2 (± 19.18)	55.3 (± 16.49)		
Change at Week 100	23.1 (± 21.82)	16.6 (± 21.92)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 124

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 124[47]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 124. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 124

Notes:

[47] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	54	43
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.33 (± 1.271)	7.24 (± 1.329)	7.61 (± 1.406)	8.14 (± 1.457)
Change at Week 124	-1.52 (± 1.805)	-1.07 (± 1.566)	-1.52 (± 1.539)	-1.70 (± 1.655)

End point values	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13011	Vedolizumab 300 mg (C13011

	Vedolizumab Q8W)	Vedolizumab Q4W)	Placebo)	Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	47	48	80	83
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.62 (± 1.423)	7.69 (± 1.446)	7.73 (± 1.441)	7.65 (± 1.510)
Change at Week 124	-1.60 (± 1.690)	-1.69 (± 1.560)	-0.85 (± 1.662)	-1.05 (± 1.637)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	97	98		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.28 (± 1.223)	7.54 (± 1.401)		
Change at Week 124	-1.34 (± 1.560)	-1.07 (± 1.639)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 124

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 124[48]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 124. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 124

Notes:

[48] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	58	54	47
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	61.2 (± 21.60)	61.6 (± 16.98)	52.0 (± 16.58)	54.8 (± 17.87)
Change at Week 124	24.0 (± 25.45)	19.7 (± 18.12)	23.8 (± 21.39)	28.1 (± 20.71)

End point values	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	82	42	47	79
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	52.8 (± 19.62)	50.0 (± 16.87)	52.4 (± 19.58)	51.8 (± 16.77)
Change at Week 124	23.8 (± 21.41)	29.4 (± 21.15)	24.5 (± 28.36)	21.1 (± 21.77)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	96	95		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	56.1 (± 20.59)	55.6 (± 15.81)		
Change at Week 124	22.2 (± 26.13)	18.1 (± 24.00)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 148

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 148[49]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none,

2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 148. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 148

Notes:

[49] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	54	53	41
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.33 (± 1.271)	7.20 (± 1.337)	7.64 (± 1.415)	8.17 (± 1.447)
Change at Week 148	-1.30 (± 1.589)	-1.26 (± 1.544)	-1.62 (± 1.417)	-1.66 (± 1.559)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	46	76	83
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.60 (± 1.450)	7.65 (± 1.370)	7.75 (± 1.434)	7.72 (± 1.541)
Change at Week 148	-1.74 (± 1.774)	-1.67 (± 1.175)	-1.11 (± 1.740)	-1.36 (± 1.679)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	94	93		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.31 (± 1.376)	7.52 (± 1.396)		

Change at Week 148	-1.47 (± 1.591)	-1.24 (± 1.644)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 148

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 148[50]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 148. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 148

Notes:

[50] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	54	53	43
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	61.2 (± 21.60)	61.5 (± 17.24)	51.4 (± 16.62)	54.3 (± 18.04)
Change at Week 148	23.4 (± 27.31)	21.9 (± 18.53)	28.7 (± 19.43)	28.2 (± 21.30)

End point values	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	83	40	45	75
Units: score on a scale				

arithmetic mean (standard deviation)				
Baseline	52.0 (± 19.73)	49.4 (± 17.04)	52.1 (± 19.63)	51.5 (± 16.66)
Change at Week 148	24.6 (± 22.24)	28.2 (± 20.56)	24.7 (± 22.11)	24.9 (± 25.63)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	92	91		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	56.2 (± 20.93)	55.6 (± 16.31)		
Change at Week 148	23.9 (± 23.40)	21.1 (± 22.50)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 172

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 172[51]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 172. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 172

Notes:

[51] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	53	49	43
Units: score on a scale				

arithmetic mean (standard deviation)				
Baseline	7.65 (± 1.446)	7.17 (± 1.326)	7.67 (± 1.449)	7.70 (± 1.337)
Change at Week 172	-1.74 (± 1.747)	-1.19 (± 1.665)	-1.45 (± 1.569)	-1.72 (± 1.098)

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	75	91	81
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.28 (± 1.308)	7.81 (± 1.548)	7.33 (± 1.407)	7.62 (± 1.428)
Change at Week 172	-1.24 (± 1.535)	-1.27 (± 1.695)	-1.52 (± 1.546)	-1.23 (± 1.653)

End point values	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13011 Placebo)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	38	70		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	8.03 (± 1.385)	7.71 (± 1.436)		
Change at Week 172	-1.76 (± 1.747)	-1.07 (± 1.722)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 172

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 172[52]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 172. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 172

Notes:

[52] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)	Vedolizumab 300 mg (C13006 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	53	80	25
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	54.2 (± 17.79)	62.1 (± 16.84)	55.4 (± 15.90)	61.6 (± 22.40)
Change at Week 172	29.4 (± 21.40)	20.3 (± 21.59)	22.2 (± 21.21)	19.8 (± 27.91)

End point values	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	75	38	70	48
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	50.9 (± 19.40)	49.7 (± 17.87)	51.3 (± 16.58)	51.3 (± 16.87)
Change at Week 172	23.9 (± 23.72)	29.2 (± 22.92)	26.0 (± 20.30)	25.9 (± 21.53)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	90		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	52.4 (± 20.42)	55.9 (± 20.95)		
Change at Week 172	25.9 (± 25.70)	25.2 (± 22.04)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 196

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 196[53]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 196. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 196

Notes:

[53] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	37	50	46
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.33 (± 1.271)	8.11 (± 1.487)	7.14 (± 1.325)	7.54 (± 1.312)
Change at Week 196	-1.30 (± 1.436)	-1.89 (± 1.449)	-1.06 (± 1.490)	-1.52 (± 1.426)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41	41	66	71
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.68 (± 1.474)	7.66 (± 1.389)	7.71 (± 1.476)	7.82 (± 1.579)
Change at Week 196	-1.85 (± 1.783)	-1.90 (± 1.375)	-1.12 (± 1.687)	-1.42 (± 1.555)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	51		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.34 (± 1.292)	7.61 (± 1.297)		
Change at Week 196	-1.44 (± 1.656)	-1.37 (± 1.697)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 196

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 196[54]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 196. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 196

Notes:

[54] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	37	50	46
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	61.2 (± 21.60)	49.0 (± 18.41)	61.3 (± 16.63)	52.5 (± 17.01)
Change at Week 196	22.9 (± 28.01)	31.9 (± 23.39)	21.6 (± 17.20)	26.4 (± 20.17)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	41	41	66	71
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	54.2 (± 17.71)	52.8 (± 20.56)	51.5 (± 16.72)	51.5 (± 19.58)
Change at Week 196	29.1 (± 22.45)	29.2 (± 22.32)	24.6 (± 21.32)	23.3 (± 26.17)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	51		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	56.7 (± 20.21)	56.5 (± 14.35)		
Change at Week 196	22.1 (± 22.91)	23.2 (± 18.14)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 248

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 248[55]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 248. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 248

Notes:

[55] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	21	38	36	32
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.48 (± 1.365)	7.21 (± 1.119)	7.69 (± 1.215)	8.09 (± 1.510)
Change at Week 248	-1.67 (± 1.653)	-1.03 (± 1.619)	-1.58 (± 1.339)	-2.03 (± 1.425)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	31	38	45
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.66 (± 1.450)	7.84 (± 1.463)	7.63 (± 1.532)	7.89 (± 1.541)
Change at Week 248	-1.81 (± 1.554)	-1.97 (± 1.538)	-1.05 (± 2.039)	-1.57 (± 1.521)

End point values	Vedolizumab 300 mg (C13008 De Novo Participants - UC)	Vedolizumab 300 mg (C13008 De Novo Participants - CD)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	4		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.33 (± 1.155)	7.75 (± 1.500)		
Change at Week 248	-2.00 (± 1.000)	-2.00 (± 1.414)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 248

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 248[56]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007, C13011 and de novo participants who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies and de novo participants for whom data was collected at both Baseline and Week 248. Not applicable for Vedolizumab 300 mg (C13004) arm group.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 248

Notes:

[56] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)	Vedolizumab 300 mg (C13007 Vedolizumab Q8W)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	21	36	32	32
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	57.2 (± 21.28)	52.1 (± 16.63)	47.2 (± 18.17)	52.3 (± 16.40)
Change at Week 248	27.5 (± 25.77)	28.0 (± 22.14)	34.9 (± 18.79)	32.1 (± 19.98)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab Q4W)	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)	Vedolizumab 300 mg (C13008 De Novo Participants - UC)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	31	38	45	3
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	53.2 (± 19.72)	50.8 (± 17.39)	49.0 (± 19.37)	61.3 (± 28.11)
Change at Week 248	29.9 (± 24.37)	24.7 (± 25.34)	28.9 (± 27.65)	28.7 (± 32.72)

End point values	Vedolizumab 300 mg (C13008 De Novo	Vedolizumab 300 mg (C13006 Vedolizumab		

	Participants - CD)	Q8W)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	37		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	47.5 (± 7.33)	61.6 (± 16.17)		
Change at Week 248	34.3 (± 11.44)	17.7 (± 18.62)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 300

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 300[57]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 300. Not applicable for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 300

Notes:

[57] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	14	13	9
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	8.14 (± 1.069)	7.50 (± 0.941)	8.08 (± 1.115)	8.33 (± 1.803)
Change at Week 300	-2.29 (± 1.799)	-1.43 (± 2.065)	-1.77 (± 1.363)	-2.11 (± 1.965)

End point values	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13011	Vedolizumab 300 mg (C13011

	Vedolizumab Q8W)	Vedolizumab Q4W)	Placebo)	Vedolizumab)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	16	4	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	7.88 (± 1.356)	7.94 (± 1.063)	7.75 (± 2.062)	7.00 (± 0.000)
Change at Week 300	-2.00 (± 2.138)	-2.25 (± 1.438)	-1.50 (± 1.291)	0.50 (± 2.121)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in EuroQol 5D Health States (EQ-5D) Visual Analog Scale (VAS) Score at Week 300

End point title	Change from Baseline in EuroQol 5D Health States (EQ-5D) Visual Analog Scale (VAS) Score at Week 300[58]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006, C13007 and C13011 who received vedolizumab in study C13008. Data is provided for participants who were completers in previous studies with data available at both Baseline and Week 300. Not applicable for Vedolizumab 300 mg (C13004) arm group. Data is not available for de novo participants at this time point.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 300

Notes:

[58] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	14	13	9
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	58.1 (± 20.27)	64.9 (± 11.82)	55.7 (± 10.10)	50.4 (± 22.34)
Change at Week 300	23.6 (± 29.14)	20.4 (± 17.92)	28.4 (± 14.78)	33.2 (± 25.83)

End point values	Vedolizumab 300 mg (C13007 Vedolizumab	Vedolizumab 300 mg (C13007 Vedolizumab	Vedolizumab 300 mg (C13011 Placebo)	Vedolizumab 300 mg (C13011 Vedolizumab)

	Q8W)	Q4W)		
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	16	4	2
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	53.1 (± 15.80)	42.9 (± 19.54)	43.5 (± 19.12)	52.0 (± 24.04)
Change at Week 300	31.3 (± 17.47)	43.6 (± 23.17)	40.3 (± 9.50)	13.0 (± 11.31)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 352

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Composite Score at Week 352[59]

End point description:

EQ-5D health states questionnaire is an instrument used to measure general HRQOL in participants with IBD. It considers five attributes of quality of life evaluation: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension has three possible levels: 1=none, 2=moderate or 3=extreme. A composite EQ-5D score can be calculated from the individual scores to assess overall HRQOL. A decrease of ≥0.3 points in the composite EQ-5D score represents improvement in quality of life of participants. A negative change from Baseline indicates improvement. ITT population from studies C13006 and C13007 who received vedolizumab in study C13008. Data is provided for completers in previous studies with data available at both Baseline and Week 352. NA for Vedolizumab 300 mg (C13004) arm group. Data is not available for C13011 Placebo and Vedolizumab arm groups and de novo participants at this time point. Here, 9999=SD was not calculated for 1 participant.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 352

Notes:

[59] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	3	1
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	8.00 (± 9999)	8.00 (± 9999)	8.33 (± 0.577)	12.00 (± 9999)
Change at Week 352	-2.00 (± 9999)	-3.00 (± 9999)	-1.33 (± 1.528)	-6.00 (± 9999)

End point values	Vedolizumab 300 mg (C13007	Vedolizumab 300 mg (C13007		

	Vedolizumab Q8W)	Vedolizumab Q4W)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	8.00 (± 1.414)	9.00 (± 9999)		
Change at Week 352	-1.00 (± 0.000)	-4.00 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 352

End point title	Change from Baseline in European Quality of Life 5-Dimension (EQ-5D) Health States Visual Analog Scale (VAS) Score at Week 352[60]

End point description:

EQ-5D questionnaire is an instrument used to measure general HRQOL in participants with IBD. Each dimension has three possible levels: 1 = none, 2 = moderate or 3 = extreme. The EQ-5D VAS score is a self-assigned rating of overall health using a 20-cm visual, vertical scale, with a score of 0 as the worst and 100 as the best possible health. An increase of ≥7 points in the EQ-5D VAS score represents a clinically meaningful improvement in quality of life for participants. A positive change from Baseline indicates improvement. ITT population from studies C13006 and C13007 who received vedolizumab in study C13008. Data is provided for completers in previous studies with data available at both Baseline and Week 352. NA for Vedolizumab 300 mg (C13004) arm group. Data is not available for C13011 Placebo and Vedolizumab arm groups and de novo participants at this time point. Here, 9999=SD was not calculated for 1 participant.

End point type	Primary

End point timeframe:

Baseline (prior to first dose of study drug in C13008; for rollover participants this was the last assessment from the previous study) and Week 352

Notes:

[60] - 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: Statistical analysis was not planned for this endpoint.

End point values	Vedolizumab 300 mg (C13006 Placebo)	Vedolizumab 300 mg (C13006 Vedolizumab Q8W)	Vedolizumab 300 mg (C13006 Vedolizumab Q4W)	Vedolizumab 300 mg (C13007 Placebo)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	3	1
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	52.0 (± 9999)	50.0 (± 9999)	48.0 (± 8.19)	15.0 (± 9999)
Change at Week 352	46.0 (± 9999)	40.0 (± 9999)	24.3 (± 20.11)	64.0 (± 9999)

End point values	Vedolizumab 300 mg	Vedolizumab 300 mg		

	(C13007 Vedolizumab Q8W)	(C13007 Vedolizumab Q4W)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	1		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	50.0 (± 14.14)	31.0 (± 9999)		
Change at Week 352	24.0 (± 8.49)	59.0 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug in this study through 16 weeks after the last dose of study drug (Up to approximately 8.5 years)

Adverse event reporting additional description:

At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups

Reporting group title	Vedolizumab 300 mg

Reporting group description:

Vedolizumab 300 mg, 30-minute IV infusion, Q4W, up to approximately 260 weeks. Includes De Novo participants and participants previously enrolled in studies C13004, C13006, C13007 and C13011.

Serious adverse events	Vedolizumab 300 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	825 / 2243 (36.78%)		
number of deaths (all causes)	10		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	2 / 4		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			

subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour of the appendix			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic neoplasm malignant	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was related.		
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	1 / 1		
Haemangioma of liver			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leiomyosarcoma	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and is not related.		
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Colon adenoma			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal meningioma benign			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to peritoneum			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Neurilemmoma			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			

subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leiomyoma			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thyroid adenoma			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thyroid cancer			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal neoplasm			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer metastatic			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal cord neoplasm			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder neoplasm				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thyroid neoplasm				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple myeloma				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder papilloma				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Axillary vein thrombosis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				

subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Subclavian vein thrombosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis superficial			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral vascular disorder			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral arterial stenosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	7 / 2243 (0.31%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Asthenia			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hernia obstructive			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza like illness			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudopolyp			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
No therapeutic response			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malaise			

subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Serum sickness			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Dysfunctional uterine bleeding			
subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Metrorrhagia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervical dysplasia			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Uterine cervical erosion			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Menorrhagia				
subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ovarian adhesion				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian mass				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Female genital tract fistula				
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Breast haematoma				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cystocele				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine polyp				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vaginal haemorrhage				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic ovarian cyst				

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatitis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Pulmonary embolism	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was not related.			
subjects affected / exposed	10 / 2243 (0.45%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 1			
Pneumothorax				
subjects affected / exposed	4 / 2243 (0.18%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Hydropneumothorax				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	4 / 2243 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Bronchial hyperreactivity				

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was not related.			
subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Acute respiratory failure				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Productive cough				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nasal septum deviation				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atelectasis				

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillar hypertrophy				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperventilation				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sleep apnoea syndrome				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Depression				
subjects affected / exposed	4 / 2243 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Stress				

subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Homicidal ideation				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Affective disorder				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Alcohol abuse				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Completed suicide	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was not related.			
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Psychotic disorder				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Weight decreased				

subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Blood glucose increased				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
C-reactive protein increased				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoglobin decreased				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Liver function test abnormal				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphocyte count decreased				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Intestinal anastomosis complication				

subjects affected / exposed	6 / 2243 (0.27%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stoma complication			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Abdominal wound dehiscence			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal anastomotic leak			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Anastomotic stenosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Procedural site reaction			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural discharge			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural pain			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Meniscus lesion			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			

subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Traumatic lung injury			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dislocation of vertebra			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intentional overdose			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acetabulum fracture			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pubis fracture			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Accidental poisoning				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Splenic rupture				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haemorrhage	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was not related.			
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Joint dislocation				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendon injury				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urethral injury			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Skeletal injury			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Vitello-intestinal duct remnant			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Angina pectoris			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Myopericarditis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriospasm coronary				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebrovascular accident	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was not related.			
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Subarachnoid haemorrhage				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	4 / 2243 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Lumbar radiculopathy				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
VIIth nerve paralysis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Grand mal convulsion			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Transient global amnesia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Migraine			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple sclerosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Optic neuritis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cervicobrachial syndrome				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracranial hypotension				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	14 / 2243 (0.62%)			
occurrences causally related to treatment / all	2 / 18			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	5 / 2243 (0.22%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				

Vertigo positional			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tinnitus			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Uveitis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vitreous floaters			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cataract			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vision blurred			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	225 / 2243 (10.03%)		
occurrences causally related to treatment / all	15 / 277		
deaths causally related to treatment / all	0 / 0		

Enteritis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epiploic appendagitis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal inflammation				
subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pouchitis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
subjects affected / exposed	120 / 2243 (5.35%)			
occurrences causally related to treatment / all	5 / 144			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	50 / 2243 (2.23%)			
occurrences causally related to treatment / all	2 / 60			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				

subjects affected / exposed	6 / 2243 (0.27%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	29 / 2243 (1.29%)		
occurrences causally related to treatment / all	0 / 38		
deaths causally related to treatment / all	0 / 0		
Ileal stenosis			
subjects affected / exposed	14 / 2243 (0.62%)		
occurrences causally related to treatment / all	1 / 14		
deaths causally related to treatment / all	0 / 0		
Small intestinal stenosis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	17 / 2243 (0.76%)		
occurrences causally related to treatment / all	2 / 19		
deaths causally related to treatment / all	0 / 0		
Intestinal stenosis			
subjects affected / exposed	6 / 2243 (0.27%)		
occurrences causally related to treatment / all	2 / 6		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	8 / 2243 (0.36%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Subileus			

subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	15 / 2243 (0.67%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Enterocolonic fistula			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Enterocutaneous fistula			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Enterovesical fistula			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	10 / 2243 (0.45%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	7 / 2243 (0.31%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	9 / 2243 (0.40%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			

subjects affected / exposed	6 / 2243 (0.27%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Intestinal haemorrhage			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colonic stenosis			
subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	1 / 5		
deaths causally related to treatment / all	0 / 0		
Colonic obstruction			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Haematochezia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	6 / 2243 (0.27%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Colon dysplasia			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia obstructive			

subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Anal stenosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal stenosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Food poisoning			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Stomatitis			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Proctalgia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal ischaemia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Megacolon			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Periproctitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal fistula			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectourethral fistula			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia strangulated			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal inflammation			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Faecaloma			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Irritable bowel syndrome			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia, obstructive			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	7 / 2243 (0.31%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	7 / 2243 (0.31%)		
occurrences causally related to treatment / all	2 / 7		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholangitis sclerosing			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			

subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Jaundice			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Systemic lupus erythematosus rash			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyoderma gangrenosum			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Erythema multiforme			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Dermal cyst			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scar			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	11 / 2243 (0.49%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Dysuria			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder hypertrophy			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder prolapse			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			

subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ureteric stenosis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urethral prolapse				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Calculus ureteric				
subjects affected / exposed	4 / 2243 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Renal failure acute				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion				
subjects affected / exposed	5 / 2243 (0.22%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Joint effusion				

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fistula			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fistula discharge			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ankylosing spondylitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Spondyloarthropathy			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Osteoporosis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myalgia			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Muscle disorder			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dupuytren's contracture				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chondropathy				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Anal abscess				
subjects affected / exposed	33 / 2243 (1.47%)			
occurrences causally related to treatment / all	3 / 35			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	19 / 2243 (0.85%)			
occurrences causally related to treatment / all	2 / 19			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	17 / 2243 (0.76%)			
occurrences causally related to treatment / all	4 / 18			
deaths causally related to treatment / all	0 / 0			
Abdominal abscess				

subjects affected / exposed	13 / 2243 (0.58%)		
occurrences causally related to treatment / all	5 / 13		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Diarrhoea infectious			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal wall abscess			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Enterocolitis infectious			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and is not related.			
subjects affected / exposed	21 / 2243 (0.94%)			
occurrences causally related to treatment / all	10 / 22			
deaths causally related to treatment / all	0 / 1			
Lobar pneumonia				
subjects affected / exposed	2 / 2243 (0.09%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	11 / 2243 (0.49%)			
occurrences causally related to treatment / all	5 / 11			
deaths causally related to treatment / all	0 / 0			
Clostridial infection				
subjects affected / exposed	5 / 2243 (0.22%)			
occurrences causally related to treatment / all	3 / 5			
deaths causally related to treatment / all	0 / 0			
Clostridium colitis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	7 / 2243 (0.31%)		
occurrences causally related to treatment / all	5 / 7		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal cellulitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was not related.		
subjects affected / exposed	6 / 2243 (0.27%)		
occurrences causally related to treatment / all	1 / 7		
deaths causally related to treatment / all	0 / 1		
Septic shock			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal sepsis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			

subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			

subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic abscess			
subjects affected / exposed	4 / 2243 (0.18%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Abscess			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blister infected			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pilonidal cyst			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			

subjects affected / exposed	5 / 2243 (0.22%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus colitis			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	3 / 2243 (0.13%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Oesophageal candidiasis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Klebsiella infection			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Klebsiella sepsis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess jaw			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Campylobacter intestinal infection				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cryptosporidiosis infection				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tooth abscess				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious mononucleosis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Vulval abscess				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
West Nile viral infection	Additional description: One treatment-emergent death occurred during treatment with vedolizumab 300 mg and was related.			
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Giardiasis				

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangitis suppurative			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes simplex			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psoas abscess			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Tinea pedis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infusion site infection			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vulval cellulitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterocolitis viral			

subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute sinusitis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative abscess			
subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Incision site infection			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peridiverticular abscess			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			

subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster ophthalmic				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear infection				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mastoiditis				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	6 / 2243 (0.27%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Malnutrition				
subjects affected / exposed	3 / 2243 (0.13%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	5 / 2243 (0.22%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Hypoalbuminaemia				
subjects affected / exposed	1 / 2243 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Obesity				

subjects affected / exposed	2 / 2243 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoproteinaemia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iron deficiency			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	1 / 2243 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Vedolizumab 300 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1820 / 2243 (81.14%)		
Nervous system disorders			
Headache			
subjects affected / exposed	452 / 2243 (20.15%)		
occurrences (all)	985		
Dizziness			
subjects affected / exposed	162 / 2243 (7.22%)		
occurrences (all)	227		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	277 / 2243 (12.35%)		
occurrences (all)	425		
Fatigue			
subjects affected / exposed	229 / 2243 (10.21%)		
occurrences (all)	344		
Influenza like illness			
subjects affected / exposed	148 / 2243 (6.60%)		
occurrences (all)	203		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	181 / 2243 (8.07%)		
occurrences (all)	259		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	393 / 2243 (17.52%)		
occurrences (all)	723		
Crohn's disease			
subjects affected / exposed	333 / 2243 (14.85%)		
occurrences (all)	489		
Nausea			
subjects affected / exposed	333 / 2243 (14.85%)		
occurrences (all)	543		
Diarrhoea			

subjects affected / exposed	284 / 2243 (12.66%)		
occurrences (all)	401		
Colitis ulcerative			
subjects affected / exposed	251 / 2243 (11.19%)		
occurrences (all)	388		
Vomiting			
subjects affected / exposed	227 / 2243 (10.12%)		
occurrences (all)	354		
Abdominal pain upper			
subjects affected / exposed	139 / 2243 (6.20%)		
occurrences (all)	203		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	251 / 2243 (11.19%)		
occurrences (all)	323		
Oropharyngeal pain			
subjects affected / exposed	168 / 2243 (7.49%)		
occurrences (all)	215		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	153 / 2243 (6.82%)		
occurrences (all)	202		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	122 / 2243 (5.44%)		
occurrences (all)	151		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	482 / 2243 (21.49%)		
occurrences (all)	808		
Back pain			
subjects affected / exposed	239 / 2243 (10.66%)		
occurrences (all)	342		
Myalgia			

subjects affected / exposed	121 / 2243 (5.39%)		
occurrences (all)	151		
Pain in extremity			
subjects affected / exposed	125 / 2243 (5.57%)		
occurrences (all)	165		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	594 / 2243 (26.48%)		
occurrences (all)	1380		
Upper respiratory tract infection			
subjects affected / exposed	379 / 2243 (16.90%)		
occurrences (all)	745		
Sinusitis			
subjects affected / exposed	235 / 2243 (10.48%)		
occurrences (all)	375		
Bronchitis			
subjects affected / exposed	216 / 2243 (9.63%)		
occurrences (all)	331		
Gastroenteritis			
subjects affected / exposed	216 / 2243 (9.63%)		
occurrences (all)	332		
Influenza			
subjects affected / exposed	208 / 2243 (9.27%)		
occurrences (all)	279		
Urinary tract infection			
subjects affected / exposed	175 / 2243 (7.80%)		
occurrences (all)	275		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 October 2008	• The primary change in this amendment involved the assessment of whether or not to analyze any antivedolizumab antibodies (AVA) -positive samples for neutralizing AVA. • Corrected the value for absolute lymphocyte count in the leukopenia and lymphopenia monitoring section. • Expanded the definition of serious adverse event (AEs) (SAE) to include any event that involves suspected transmission of an infectious agent via a medicinal product.
28 April 2009	• The primary change in this amendment involved extending the window for participants to enroll in this study after the last dose of vedolizumab in Study C13004 from 5 to 9 weeks. • Revised the definition of rescue medications with all applicable exceptions, ie, to allow use of rectal steroids, 5-acetyl salicylic acid, and probiotics for all participants and allow use of antibiotics for Crohn's disease participants. • Revised inclusion criteria by removing the requirement of "stable dose" for participants on corticosteroids at the time of enrollment. • Revised the advice regarding prophylactic administration of premedication for better clarity. • Removed language regarding the transfer of adverse events and SAE information from the previous study to the C13008 electronic case report form. • Removed an unnecessary statement regarding the reporting of malignancies, as the reporting of malignancies is governed by the definitions and reporting requirements of AEs and SAEs. • Removed statements regarding pharmacodynamic sampling and objectives. There were no pharmacodynamic objectives or pharmacodynamic samples to be collected in this study at any time.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported