Clinical trial results:
Post-Marketing Observational Cohort Study of Patients with Inflammatory Bowel Disease (IBD) Treated With CT-P13 in Usual Clinical Practice(CONNECT-IBD)

Summary

EudraCT number	2014-005192-89
Trial protocol	FI
Global end of trial date	31 October 2018

Results information

Result version number	v1 (current)
This version publication date	06 February 2022
First version publication date	06 February 2022

Trial information

Trial identification

Sponsor protocol code	C1231001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02539368
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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	20 August 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterise the population and drug utilisation patterns of patients treated with CT-P13 for CD or UC in the context of SOC Remicade and to explore the long-term safety profile of CT-P13 in the treatment of patients with CD or UC in the context of SOC Remicade.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 April 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 23
Country: Number of subjects enrolled	Czechia: 36
Country: Number of subjects enrolled	Finland: 38
Country: Number of subjects enrolled	France: 622
Country: Number of subjects enrolled	Germany: 623
Country: Number of subjects enrolled	Greece: 87
Country: Number of subjects enrolled	Hungary: 56
Country: Number of subjects enrolled	Italy: 257
Country: Number of subjects enrolled	Netherlands: 54
Country: Number of subjects enrolled	Portugal: 54
Country: Number of subjects enrolled	Slovakia: 60
Country: Number of subjects enrolled	Spain: 451
Country: Number of subjects enrolled	United Kingdom: 182
Worldwide total number of subjects	2543
EEA total number of subjects	2361

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)	2387
From 65 to 84 years	152
85 years and over	4

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 2565 subjects were enrolled in the study, out of which 22 subjects were not eligible to receive treatment for any of the treatment groups. Hence, only those subjects who received treatment during the study observation period were included in the subjects flow section.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P13

Arm description:

Subjects diagnosed with either Crohn’s Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months.

Arm type	Experimental
Investigational medicinal product name	Infliximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate
Routes of administration	Intravenous use

Dosage and administration details:

Infliximab was administered following local standard of care. As per summary of product characteristics:
Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the
first infusion.
Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and
6 weeks after the first infusion, then every 8 weeks thereafter.

Arm title	Remicade

Arm description:

Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months.

Arm type	Experimental

Investigational medicinal product name	Remicade
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate
Routes of administration	Intravenous use

Dosage and administration details:

Remicade was administered following local standard of care. As per summary of product characteristics:
Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the
first infusion.
Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and
6 weeks after the first infusion, then every 8 weeks thereafter.

Arm title	Switched From Remicade to CT-P13

Arm description:

Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months.

Arm type	Experimental
Investigational medicinal product name	Infliximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate
Routes of administration	Intravenous use

Dosage and administration details:

Infliximab was administered following local standard of care. As per summary of product characteristics:
Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the
first infusion.
Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and
6 weeks after the first infusion, then every 8 weeks thereafter.

Arm title	Switched From CT-P13 to Remicade

Arm description:

Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months.

Arm type	Experimental
Investigational medicinal product name	Remicade
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate
Routes of administration	Intravenous use

Dosage and administration details:

Remicade was administered following local standard of care. As per summary of product characteristics:
Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the
first infusion.
Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and
6 weeks after the first infusion, then every 8 weeks thereafter.

Arm title	Multiple Switchers

Arm description:

Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD.

Arm type	Experimental

Investigational medicinal product name	Remicade
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate
Routes of administration	Intravenous use

Dosage and administration details:

Remicade was administered following local standard of care. As per summary of product characteristics:
Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the
first infusion.
Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and
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Infliximab was administered following local standard of care. As per summary of product characteristics:
Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the
first infusion.
Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and
6 weeks after the first infusion, then every 8 weeks thereafter.

Number of subjects in period 1	CT-P13	Remicade	Switched From Remicade to CT-P13
Started	1522	494	358
Completed	1117	393	291
Not completed	405	101	67
Adverse event, serious fatal	4	2	1
Consent withdrawn by subject	44	35	9
Physician decision	49	15	7
Subject Non-compliant	13	2	1
Adverse event, non-fatal	44	5	9
Unspecified	145	18	24
Lost to follow-up	96	21	16
Missing	10	3	-

Number of subjects in period 1	Switched From CT-P13 to Remicade	Multiple Switchers
Started	67	102
Completed	60	88
Not completed	7	14
Adverse event, serious fatal	-	-
Consent withdrawn by subject	1	3
Physician decision	-	2

Subject Non-compliant	1	-
Adverse event, non-fatal	-	3
Unspecified	1	3
Lost to follow-up	4	3
Missing	-	-

Baseline characteristics

Reporting groups	
Reporting group title	CT-P13
Reporting group description:	
Subjects diagnosed with either Crohn's Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months.	
Reporting group title	Remicade
Reporting group description:	
Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months.	
Reporting group title	Switched From Remicade to CT-P13
Reporting group description:	
Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months.	
Reporting group title	Switched From CT-P13 to Remicade
Reporting group description:	
Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months.	
Reporting group title	Multiple Switchers
Reporting group description:	
Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD.	

Reporting group values	CT-P13	Remicade	Switched From Remicade to CT-P13
Number of subjects	1522	494	358
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1420	474	331
From 65-84 years	99	20	27
85 years and over	3	0	0

Age Continuous Units: years			
arithmetic mean	39.8	38.8	40.9
standard deviation	± 14.65	± 12.74	± 14.14
Sex: Female, Male Units: Subjects			
Female	750	233	158
Male	772	261	200
Subjects With Medical History of Smoking Units: Subjects			
Subjects With Smoking History	320	94	70
Subjects with no Smoking History	1202	400	288
Subjects With a History of Cancer Units: Subjects			
Subjects With Cancer History	41	10	6
Subjects with no Cancer History	1481	484	352
Subjects With Stoma Status Units: Subjects			
Subjects With Stoma Status	33	13	14
Subjects With no Stoma Status	1489	481	344
Subjects With a History Surgery			
Surgery status was a categorical variable defined as yes if the subject had prior surgical treatment related to the treatment of CD or UC.			
Units: Subjects			
Subjects With Surgery History	395	165	116
Subjects With no Surgery History	1127	329	242
Subjects With a History of Fistula Disease Units: Subjects			
Subjects With History of Fistula Disease	304	124	86
Subjects With no History of Fistula Disease	1218	370	272
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	4	1	0
Asian	5	3	5
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	7	0	1
White	1080	391	275
Other	267	60	49
Unknown or Not Reported	158	39	28

Reporting group values	Switched From CT-P13 to Remicade	Multiple Switchers	Total
Number of subjects	67	102	2543
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	65	97	2387
From 65-84 years	2	4	152
85 years and over	0	1	4
Age Continuous			
Units: years			
arithmetic mean	41.1	38.4	
standard deviation	± 13.96	± 13.23	-
Sex: Female, Male			
Units: Subjects			
Female	29	48	1218
Male	38	54	1325
Subjects With Medical History of Smoking			
Units: Subjects			
Subjects With Smoking History	12	17	513
Subjects with no Smoking History	55	85	2030
Subjects With a History of Cancer			
Units: Subjects			
Subjects With Cancer History	1	4	62
Subjects with no Cancer History	66	98	2481
Subjects With Stoma Status			
Units: Subjects			
Subjects With Stoma Status	3	2	65
Subjects With no Stoma Status	64	100	2478
Subjects With a History Surgery			
Surgery status was a categorical variable defined as yes if the subject had prior surgical treatment related to the treatment of CD or UC.			
Units: Subjects			
Subjects With Surgery History	23	32	731
Subjects With no Surgery History	44	70	1812
Subjects With a History of Fistula Disease			
Units: Subjects			
Subjects With History of Fistula Disease	19	28	561
Subjects With no History of Fistula Disease	48	74	1982
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	0	0	5
Asian	0	0	13
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	0	0	8
White	55	83	1884
Other	11	14	401
Unknown or Not Reported	1	5	231

End points

End points reporting groups

Reporting group title	CT-P13

Reporting group description:

Subjects diagnosed with either Crohn’s Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months.

Reporting group title	Remicade

Reporting group description:

Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months.

Reporting group title	Switched From Remicade to CT-P13

Reporting group description:

Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months.

Reporting group title	Switched From CT-P13 to Remicade

Reporting group description:

Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months.

Reporting group title	Multiple Switchers

Reporting group description:

Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD.

Primary: Disease Characteristics of Subjects: Disease Duration

End point title	Disease Characteristics of Subjects: Disease Duration[1]

End point description:

Disease duration was defined as the number of months from initial diagnosis of inflammatory bowel disease (CD or UC) to the date of informed consent, which was recorded at the time of enrollment into the study (baseline). Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this end point.

End point type	Primary

End point timeframe:

Baseline (Day 1)

Notes:

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

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1519	494	358	67
Units: months				
median (full range (min-max))	63.0 (0 to 579)	112.5 (0 to 632)	120.0 (2 to 593)	86.0 (0 to 519)

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: months				
median (full range (min-max))	101.0 (9 to 457)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Switched Treatment

End point title	Number of Subjects Who Switched Treatment[2][3]

End point description:

Here, number of subjects with either UC or CD, who switched from remicade to CT-P13; switched from CT-P13 to remicade and multiple switchers were reported. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 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: No statistical analyses was planned for this end point

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

End point values	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade	Multiple Switchers	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	358	67	102	
Units: Subjects				
Crohn’s Disease	237	47	72	
Ulcerative Colitis	121	20	30	

Statistical analyses

No statistical analyses for this end point

Primary: Reasons for Switching Treatment by Subjects

End point title	Reasons for Switching Treatment by Subjects[4]

End point description:

Reasons for switch were not captured in electronic data capture. Hence, due to change in planned analysis, data was not collected and analysed.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 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: No statistical analyses was planned for this end point

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[5]	0[6]	0[7]	0[8]
Units: Subjects				

Notes:

[5] - Reasons for switch were not captured in electronic data capture.

[6] - Reasons for switch were not captured in electronic data capture.

[7] - Reasons for switch were not captured in electronic data capture.

[8] - Reasons for switch were not captured in electronic data capture.

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	0[9]			
Units: Subjects				

Notes:

[9] - Reasons for switch were not captured in electronic data capture.

Statistical analyses

No statistical analyses for this end point

Primary: Total Dose of Infusion Received

End point title	Total Dose of Infusion Received[10]

End point description:

Total dose of infusion received by the subjects was calculated. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this outcome measure. ''99999'' here signifies data was not available.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

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

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1520	493	358	67
Units: milligram				
median (full range (min-max))	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: milligram				
median (full range (min-max))	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects by Frequency of Infusion Received

End point title	Number of Subjects by Frequency of Infusion Received[11]

End point description:

Number of subjects by infusion frequency (weeks) were reported at baseline and categorized as follows: once a week; once every 2 weeks; once every 3 weeks; once every 4 weeks; once every 5 weeks; once every 6 weeks; once every 7 weeks; once every 8 weeks and others. Here, ‘Others’ category included all the frequencies apart from the mentioned categories. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this end point.

End point type	Primary

End point timeframe:

Baseline (Day 1)

Notes:

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

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1283	433	317	60
Units: Subjects				
Once a week	5	0	0	0
Once every 2 weeks	140	5	11	3

Once every 3 weeks	1	0	0	0
Once every 4 weeks	109	47	32	9
Once every 5 weeks	7	8	5	0
Once every 6 weeks	84	67	43	3
Once every 7 weeks	9	27	14	2
Once every 8 weeks	804	247	198	42
Other	124	32	14	1

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	85			
Units: Subjects				
Once a week	0			
Once every 2 weeks	3			
Once every 3 weeks	1			
Once every 4 weeks	7			
Once every 5 weeks	4			
Once every 6 weeks	15			
Once every 7 weeks	4			
Once every 8 weeks	47			
Other	4			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects who had Change in Infusion Dose

End point title	Number of Subjects who had Change in Infusion Dose[12]

End point description:

Subjects who had change in the dose of infusion (either dose reduction or increase in dose) were included and reported. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

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: No statistical analyses was planned for this end point

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1522	494	358	67
Units: Subjects	479	110	89	28

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Subjects	31			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects who had Change in Infusion Dose Categorized Based on Reasons of Change

End point title	Number of Subjects who had Change in Infusion Dose Categorized Based on Reasons of Change[13]

End point description:

Subjects who had change in infusion dose due to various reasons such as principal investigator's decision, subject's decisions, loss of response, lack of compliance, hypersensitivity, occurrence of adverse event (including adverse event special interest [AESI]/ serious adverse event [SAE]), positive for antibodies and other were reported. Here, 'Others' category included all reasons apart from the mentioned categories. A subject could have different reasons of dose change across visits, hence could be counted in more than one category. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this end point.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

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: No statistical analyses was planned for this end point

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	479	110	89	28
Units: Subjects				
Principal Investigator's Decision	213	61	31	26
Participant's Decision	5	2	0	0
Loss of response	142	27	17	3
Lack of compliance	3	1	0	0
Hypersensitivity	4	1	1	0
Occurrence of Adverse Event (including AESI/SAE)	23	3	3	0
Positive for antibodies	5	2	2	0
Other	142	26	42	2

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	31			
Units: Subjects				
Principal Investigator's Decision	16			
Participant's Decision	0			
Loss of response	12			
Lack of compliance	0			
Hypersensitivity	0			
Occurrence of Adverse Event (including AESI/SAE)	2			
Positive for antibodies	0			
Other	9			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Took Concomitant Medications Related to the Treatment of Crohn's Disease (CD) or Ulcerative Colitis (UC)

End point title	Number of Subjects Who Took Concomitant Medications Related to the Treatment of Crohn's Disease (CD) or Ulcerative Colitis (UC)[14]

End point description:

Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

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: No statistical analyses was planned for this end point

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1522	494	358	67
Units: Subjects	1025	262	187	39

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Subjects	67			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Event (AEs), Serious Adverse Events (SAEs) and Adverse Event With Special Interest (AESIs)

End point title	Number of Subjects With Treatment-Emergent Adverse Event (AEs), Serious Adverse Events (SAEs) and Adverse Event With Special Interest (AESIs)[15]

End point description:

An AE was any untoward medical occurrence in a subject who received study treatment without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death, initial or prolonged inpatient hospitalization, life-threatening experience (immediate risk of dying), persistent or significant disability or incapacity, congenital anomaly. Treatment-emergent were events between first dose of infusion up to month 24, that were absent before treatment or that worsened relative to pretreatment state. Hypersensitivity was the pre-defined TEAE of special Interest for this study. AEs included both serious and non-serious adverse events. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

End point type	Primary

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

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: No statistical analyses was planned for this end point

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1522	494	358	67
Units: Subjects				
TEAEs	621	133	130	15
SAEs	256	43	57	10
TEAEs of Special Interest	189	49	37	8

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Subjects				
TEAEs	30			
SAEs	15			
TEAEs of Special Interest	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Remaining in Clinical Remission or Relapse

End point title	Number of Subjects Remaining in Clinical Remission or Relapse

End point description:

Clinical remission: total Mayo score of 2 points or lower, with no individual sub score exceeding 1 point. An instrument designed to measure disease activity, consists of 4 sub scores: stool frequency, rectal bleeding, findings of centrally read flexible proctosigmoidoscopy and physician's global assessment, each sub score graded from 0 to 3: higher scores indicate more severe disease. The scores were added to give a total score range of 0 to 12: higher scores indicate more severe disease. The relapse of clinical remission was defined as the time from date of first attaining CR to date of relapse or death from any cause, whichever occurred first. Full analysis set (FAS)=all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to assessment of CD or UC). Number analysed =subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1516	492	358	67
Units: Subjects				
Month 6: Remission (n=1036,335,280,54,74)	870	312	261	51
Month 12: Remission (n= 914,306,240,47,64)	802	288	224	45
Month 18: Remission (n= 703,268,203,32,66)	633	257	192	31
Month 24: Remission (n= 424,191,157,24,43)	386	184	148	23
Month 6: Relapse (n=1036,335,280,54,74)	166	23	19	3
Month 12: Relapse (n= 914,306,240,47,64)	112	18	16	2
Month 18: Relapse (n= 703,268,203,32,66)	70	11	11	1
Month 24: Relapse (n= 424,191,157,24,43)	38	7	9	1

End point values	Multiple Switchers			

Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Subjects				
Month 6: Remission (n=1036,335,280,54,74)	70			
Month 12: Remission (n= 914,306,240,47,64)	58			
Month 18: Remission (n= 703,268,203,32,66)	61			
Month 24: Remission (n= 424,191,157,24,43)	39			
Month 6: Relapse (n=1036,335,280,54,74)	4			
Month 12: Relapse (n= 914,306,240,47,64)	6			
Month 18: Relapse (n= 703,268,203,32,66)	5			
Month 24: Relapse (n= 424,191,157,24,43)	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Clinical Remission

End point title	Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Clinical Remission

End point description:

HBI: simple index of CD activity, measures 5 criteria; the general well-being (0=very well to 4=terrible), abdominal pain (0=none to 3=severe), number of liquid stools per day (no maximum score), presence of an abdominal mass on physical exam (0=none to 3= definite and tender), and whether any complications 0=no complications, 1=Arthralgia; 2=Uveitis; 3=Erythema nodosum; 4=Aphthous ulcer; 5=Pyoderma gangrenosum; 6=Anal fissure; 7=New fistula 8=abscess. Total HBI score: sum of all 5 individual criteria. Minimum score: 0, no pre-specified maximum score as it depends on the number of liquid stools. Higher HBI scores=greater disease activity. Level of disease activity: CR (score less than [<] 5), MD (score equal to [=] 5-7), Mod D (score=8-16) and SD (score more than [>] 16). FAS was analyzed. "Number of Subjects Analyzed" = number of subjects evaluable for this end point; "number analysed" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	969	348	237	47
Units: Subjects				
At Baseline (n=969,348,237,47,72)	606	246	150	29
Baseline-CR; Month 6-CR (n=606,246,150,29,49)	485	211	125	24

Baseline-CR; Month 6-MD (n=606,246,150,29,49)	42	11	11	2
Baseline-CR; Month 6-Mod D (n=606,246,150,29,49)	23	8	2	1
Baseline-CR; Month 6-SD (n=606,246,150,29,49)	1	1	0	0
Baseline-CR; Month 6-Missing (n=606,246,150,29,49)	55	15	12	2
Baseline-CR; Month 12-CR (n=606,246,150,29,49)	429	182	109	22
Baseline-CR; Month 12-MD (n=606,246,150,29,49)	36	14	8	3
Baseline-CR; Month 12-Mod D (n=606,246,150,29,49)	20	4	5	1
Baseline-CR; Month 12-SD (n=606,246,150,29,49)	0	0	0	0
Baseline-CR;Month 12-Missing (n=606,246,150,29,49)	121	46	28	3
Baseline-CR; Month 18-CR (n=606,246,150,29,49)	326	143	96	17
Baseline-CR; Month 18-MD (n=606,246,150,29,49)	25	11	4	0
Baseline-CR; Month 18-Mod D (n=606,246,150,29,49)	8	4	2	0
Baseline-CR; Month 18-SD (n=606,246,150,29,49)	0	0	0	0
Baseline-CR; Month18-Missing (n=606,246,150,29,49)	247	88	48	12
Baseline-CR; Month 24-CR (n=606,246,150,29,49)	194	98	68	11
Baseline-CR; Month 24-MD (n=606,246,150,29,49)	16	7	3	1
Baseline-CR; Month 24-Mod D (n=606,246,150,29,49)	5	1	3	0
Baseline-CR; Month 24-SD (n=606,246,150,29,49)	0	0	1	0
Baseline-CR; Month24-Missing (n=606,246,150,29,49)	391	140	75	17

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: Subjects				
At Baseline (n=969,348,237,47,72)	49			
Baseline-CR; Month 6-CR (n=606,246,150,29,49)	43			
Baseline-CR; Month 6-MD (n=606,246,150,29,49)	4			
Baseline-CR; Month 6-Mod D (n=606,246,150,29,49)	0			
Baseline-CR; Month 6-SD (n=606,246,150,29,49)	0			
Baseline-CR; Month 6-Missing (n=606,246,150,29,49)	2			
Baseline-CR; Month 12-CR (n=606,246,150,29,49)	42			

Baseline-CR; Month 12-MD (n=606,246,150,29,49)	1			
Baseline-CR; Month 12-Mod D (n=606,246,150,29,49)	0			
Baseline-CR; Month 12-SD (n=606,246,150,29,49)	0			
Baseline-CR;Month 12-Missing (n=606,246,150,29,49)	6			
Baseline-CR; Month 18-CR (n=606,246,150,29,49)	37			
Baseline-CR; Month 18-MD (n=606,246,150,29,49)	1			
Baseline-CR; Month 18-Mod D (n=606,246,150,29,49)	1			
Baseline-CR; Month 18-SD (n=606,246,150,29,49)	0			
Baseline-CR; Month18-Missing (n=606,246,150,29,49)	10			
Baseline-CR; Month 24-CR (n=606,246,150,29,49)	28			
Baseline-CR; Month 24-MD (n=606,246,150,29,49)	2			
Baseline-CR; Month 24-Mod D (n=606,246,150,29,49)	0			
Baseline-CR; Month 24-SD (n=606,246,150,29,49)	0			
Baseline-CR; Month24-Missing (n=606,246,150,29,49)	19			

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Disease Activity

End point title	Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Disease Activity

End point description:

HBI: simple index of CD activity, measures 5 criteria; the general well-being (0=very well to 4=terrible), abdominal pain (0=none to 3=severe), number of liquid stools per day (no maximum score), presence of an abdominal mass on physical exam (0=none to 3= definite and tender), and whether any complications 0=no complications, 1=Arthralgia; 2=Uveitis; 3=Erythema nodosum; 4=Aphthous ulcer; 5=Pyoderma gangrenosum; 6=Anal fissure; 7=New fistula 8=abscess. Total HBI score: sum of all 5 individual criteria. Minimum score: 0, no pre-specified maximum score as it depends on the number of liquid stools. Higher HBI scores=greater disease activity. The level of disease activity was interpreted as clinical remission (CR) (HBI score < 5), mild disease (MD) (HBI score = 5 to 7), moderate disease (Mod D) (HBI score = 8 to 16) and severe disease (SD) (HBI score >16). Number analysed =subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	969	348	237	47
Units: Subjects				
At Baseline: MD (n=969,348,237,47,72)	137	45	24	10
At Baseline: Mod D (n=969,348,237,47,72)	91	22	15	4
At Baseline: SD (n=969,348,237,47,72)	6	2	0	0
Baseline-MD; Month 6-CR (n=137,45,24,10,7)	82	21	9	5
Baseline-MD; Month 6-MD (n=137,45,24,10,7)	30	13	11	4
Baseline-MD; Month 6-Mod D (n=137,45,24,10,7)	12	8	3	0
Baseline-MD; Month 6-SD (n=137,45,24,10,7)	0	0	1	0
Baseline-MD; Month 6-Missing (n=137,45,24,10,7)	13	3	0	1
Baseline-Mod D; Month 6-CR (n=91,22,15,4,3)	39	4	6	3
Baseline-Mod D; Month 6-MD (n=91,22,15,4,3)	19	6	2	1
Baseline-Mod D; Month 6-Mod D (n=91,22,15,4,3)	25	8	6	0
Baseline-Mod D; Month 6-SD (n=91,22,15,4,3)	1	0	0	0
Baseline-Mod D; Month 6-Missing (n=91,22,15,4,3)	7	4	1	0
Baseline-SD; Month 6-CR (n=6,2,0,0,0)	1	1	0	0
Baseline-SD; Month 6-MD (n=6,2,0,0,0)	2	0	0	0
Baseline-SD; Month 6-Mod D (n=6,2,0,0,0)	2	0	0	0
Baseline-SD; Month 6-SD (n=6,2,0,0,0)	0	1	0	0
Baseline-SD; Month 6-Missing (n=6,2,0,0,0)	1	0	0	0
Baseline-MD; Month 12-CR (n=137,45,24,10,7)	81	24	14	6
Baseline-MD; Month 12-MD (n=137,45,24,10,7)	16	6	3	2
Baseline-MD; Month 12-Mod D (n=137,45,24,10,7)	7	6	3	0
Baseline-MD; Month 12-SD (n=137,45,24,10,7)	1	0	0	0
Baseline-MD; Month 12-Missing (n=137,45,24,10,7)	32	9	4	2
Baseline-Mod D; Month 12-CR (n=91,22,15,4,3)	39	6	4	3
Baseline-Mod D; Month 12-MD (n=91,22,15,4,3)	15	9	0	1
Baseline-Mod D; Month 12-Mod D (n=91,22,15,4,3)	16	2	6	0
Baseline-Mod D; Month 12-SD (n=91,22,15,4,3)	0	0	0	0
Baseline-Mod D; Month 12-Missing (n=91,22,15,4,3)	21	5	5	0
Baseline-SD; Month 12-CR (n=6,2,0,0,0)	1	1	0	0
Baseline-SD; Month 12-MD (n=6,2,0,0,0)	2	0	0	0

Baseline-SD; Month 12-Mod D (n=6,2,0,0,0)	1	0	0	0
Baseline-SD; Month 12-SD (n=6,2,0,0,0)	0	1	0	0
Baseline-SD; Month 12-Missing (n=6,2,0,0,0)	2	0	0	0
Baseline-MD; Month 18-CR (n=137,45,24,10,7)	60	24	12	2
Baseline-MD; Month 18-MD (n=137,45,24,10,7)	10	6	1	4
Baseline-MD; Month 18-Mod D (n=137,45,24,10,7)	4	2	1	0
Baseline-MD; Month 18-SD (n=137,45,24,10,7)	2	0	0	0
Baseline-MD; Month 18-Missing (n=137,45,24,10,7)	61	13	10	4
Baseline-Mod D; Month 18-CR (n=91,22,15,4,3)	30	4	2	3
Baseline-Mod D; Month 18-MD (n=91,22,15,4,3)	13	7	2	1
Baseline-Mod D; Month 18-Mod D (n=91,22,15,4,3)	14	3	3	0
Baseline-Mod D; Month 18-SD (n=91,22,15,4,3)	0	0	0	0
Baseline-Mod D; Month 18-Missing (n=91,22,15,4,3)	34	8	8	0
Baseline-SD; Month 18-CR (n=6,2,0,0,0)	1	1	0	0
Baseline-SD; Month 18-MD (n=6,2,0,0,0)	2	1	0	0
Baseline-SD; Month 18-Mod D (n=6,2,0,0,0)	1	0	0	0
Baseline-SD; Month 18-SD (n=6,2,0,0,0)	0	0	0	0
Baseline-SD; Month 18-Missing (n=6,2,0,0,0)	2	0	0	0
Baseline-MD; Month 24-CR (n=137,45,24,10,7)	34	13	8	5
Baseline-MD; Month 24-MD (n=137,45,24,10,7)	15	6	2	1
Baseline-MD; Month 24-Mod D (n=137,45,24,10,7)	2	1	1	0
Baseline-MD; Month 24-SD (n=137,45,24,10,7)	1	0	0	0
Baseline-MD; Month 24-Missing (n=137,45,24,10,7)	85	25	13	4
Baseline-Mod D; Month 24-CR (n=91,22,15,4,3)	23	3	4	3
Baseline-Mod D; Month 24-MD (n=91,22,15,4,3)	5	2	1	0
Baseline-Mod D; Month 24-Mod D (n=91,22,15,4,3)	10	9	3	1
Baseline-Mod D; Month 24-SD (n=91,22,15,4,3)	1	0	0	0
Baseline-Mod D; Month 24-Missing (n=91,22,15,4,3)	52	8	7	0
Baseline-SD; Month 24-CR (n=6,2,0,0,0)	0	1	0	0
Baseline-SD; Month 24-MD (n=6,2,0,0,0)	2	0	0	0
Baseline-SD; Month 24-Mod D (n=6,2,0,0,0)	0	0	0	0

Baseline-SD; Month 24-SD (n=6,2,0,0,0)	0	1	0	0
Baseline-SD; Month 24-Missing (n=6,2,0,0,0)	4	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: Subjects				
At Baseline: MD (n=969,348,237,47,72)	7			
At Baseline: Mod D (n=969,348,237,47,72)	3			
At Baseline: SD (n=969,348,237,47,72)	0			
Baseline-MD; Month 6-CR (n=137,45,24,10,7)	3			
Baseline-MD; Month 6-MD (n=137,45,24,10,7)	1			
Baseline-MD; Month 6-Mod D (n=137,45,24,10,7)	2			
Baseline-MD; Month 6-SD (n=137,45,24,10,7)	1			
Baseline-MD; Month 6-Missing (n=137,45,24,10,7)	0			
Baseline-Mod D; Month 6-CR (n=91,22,15,4,3)	2			
Baseline-Mod D; Month 6-MD (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 6-Mod D (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 6-SD (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 6-Missing (n=91,22,15,4,3)	1			
Baseline-SD; Month 6-CR (n=6,2,0,0,0)	0			
Baseline-SD; Month 6-MD (n=6,2,0,0,0)	0			
Baseline-SD; Month 6-Mod D (n=6,2,0,0,0)	0			
Baseline-SD; Month 6-SD (n=6,2,0,0,0)	0			
Baseline-SD; Month 6-Missing (n=6,2,0,0,0)	0			
Baseline-MD; Month 12-CR (n=137,45,24,10,7)	4			
Baseline-MD; Month 12-MD (n=137,45,24,10,7)	1			
Baseline-MD; Month 12-Mod D (n=137,45,24,10,7)	1			
Baseline-MD; Month 12-SD (n=137,45,24,10,7)	1			
Baseline-MD; Month 12-Missing (n=137,45,24,10,7)	0			
Baseline-Mod D; Month 12-CR (n=91,22,15,4,3)	3			
Baseline-Mod D; Month 12-MD (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 12-Mod D (n=91,22,15,4,3)	0			

Baseline-Mod D; Month 12-SD (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 12-Missing (n=91,22,15,4,3)	0			
Baseline-SD; Month 12-CR (n=6,2,0,0,0)	0			
Baseline-SD; Month 12-MD (n=6,2,0,0,0)	0			
Baseline-SD; Month 12-Mod D (n=6,2,0,0,0)	0			
Baseline-SD; Month 12-SD (n=6,2,0,0,0)	0			
Baseline-SD; Month 12-Missing (n=6,2,0,0,0)	0			
Baseline-MD; Month 18-CR (n=137,45,24,10,7)	2			
Baseline-MD; Month 18-MD (n=137,45,24,10,7)	3			
Baseline-MD; Month 18-Mod D (n=137,45,24,10,7)	2			
Baseline-MD; Month 18-SD (n=137,45,24,10,7)	0			
Baseline-MD; Month 18-Missing (n=137,45,24,10,7)	0			
Baseline-Mod D; Month 18-CR (n=91,22,15,4,3)	2			
Baseline-Mod D; Month 18-MD (n=91,22,15,4,3)	1			
Baseline-Mod D; Month 18-Mod D (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 18-SD (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 18-Missing (n=91,22,15,4,3)	0			
Baseline-SD; Month 18-CR (n=6,2,0,0,0)	0			
Baseline-SD; Month 18-MD (n=6,2,0,0,0)	0			
Baseline-SD; Month 18-Mod D (n=6,2,0,0,0)	0			
Baseline-SD; Month 18-SD (n=6,2,0,0,0)	0			
Baseline-SD; Month 18-Missing (n=6,2,0,0,0)	0			
Baseline-MD; Month 24-CR (n=137,45,24,10,7)	2			
Baseline-MD; Month 24-MD (n=137,45,24,10,7)	2			
Baseline-MD; Month 24-Mod D (n=137,45,24,10,7)	2			
Baseline-MD; Month 24-SD (n=137,45,24,10,7)	0			
Baseline-MD; Month 24-Missing (n=137,45,24,10,7)	1			
Baseline-Mod D; Month 24-CR (n=91,22,15,4,3)	1			
Baseline-Mod D; Month 24-MD (n=91,22,15,4,3)	1			
Baseline-Mod D; Month 24-Mod D (n=91,22,15,4,3)	0			
Baseline-Mod D; Month 24-SD (n=91,22,15,4,3)	0			

Baseline-Mod D; Month 24-Missing (n=91,22,15,4,3)	1			
Baseline-SD; Month 24-CR (n=6,2,0,0,0)	0			
Baseline-SD; Month 24-MD (n=6,2,0,0,0)	0			
Baseline-SD; Month 24-Mod D (n=6,2,0,0,0)	0			
Baseline-SD; Month 24-SD (n=6,2,0,0,0)	0			
Baseline-SD; Month 24-Missing (n=6,2,0,0,0)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Clinical Remission

End point title	Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Clinical Remission

End point description:

Mayo Score: instrument to measure disease activity of UC. Score ranges: 0-12 points. There are 4 sub scores: graded from 0-3. Higher scores: more severe disease. Partial Mayo Score (PMS) (Mayo score without endoscopy) is comprised of 3 parameters: stool frequency from 0 (normal number of stools) to 3 (having >=5 stools more than normal), the presence of rectal bleeding (0=no blood seen to 3=blood alone passes), and physician's global assessment (0=normal to 3=severe disease). Total PMS: sum of all parameters, score from 0 (normal or inactive disease) to 9 (severe disease). Score was calculated if data was available for at least 1 of 3 sub scores. Level of disease activity: clinical remission (CR) (PMS <2), mild disease (MD) (PMS=2-4), moderate disease (Mod D) (PMS=5-6) and severe disease (SD) (PMS >6). FAS was analysed. "Number of Subjects Analysed" = number of subjects evaluable for this end point; "number analysed" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	547	144	121	20
Units: Subjects				
At Baseline (n=547,144,121,20,30)	169	83	55	9
Baseline-CR; Month 6-CR (n=169,83,55,9,13)	117	65	40	7
Baseline-CR; Month 6-MD (n=169,83,55,9,13)	27	9	7	2
Baseline-CR; Month 6-Mod D (n=169,83,55,9,13)	7	0	1	0
Baseline-CR; Month 6-SD (n=169,83,55,9,13)	1	0	1	0
Baseline-CR; Month 6-Missing (n=169,83,55,9,13)	17	9	6	0

Baseline-CR; Month 12-CR (n=169,83,55,9,13)	107	65	30	8
Baseline-CR; Month 12-MD (n=169,83,55,9,13)	24	4	10	0
Baseline-CR; Month 12-Mod D (n=169,83,55,9,13)	5	0	1	0
Baseline-CR; Month 12-SD (n=169,83,55,9,13)	1	0	0	0
Baseline-CR; Month 12-Missing (n=169,83,55,9,13)	32	14	14	1
Baseline-CR; Month 18-CR (n=169,83,55,9,13)	88	55	25	3
Baseline-CR; Month 18-MD (n=169,83,55,9,13)	13	8	4	0
Baseline-CR; Month 18-Mod D (n=169,83,55,9,13)	6	0	2	0
Baseline-CR; Month 18-SD (n=169,83,55,9,13)	2	0	1	0
Baseline-CR; Month 18-Missing (n=169,83,55,9,13)	60	20	23	6
Baseline-CR; Month 24-CR (n=169,83,55,9,13)	57	38	22	3
Baseline-CR; Month 24-MD (n=169,83,55,9,13)	7	5	3	0
Baseline-CR; Month 24-Mod D (n=169,83,55,9,13)	2	1	1	0
Baseline-CR; Month 24-SD (n=169,83,55,9,13)	0	0	0	0
Baseline-CR; Month 24-Missing (n=169,83,55,9,13)	103	39	29	6

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Subjects				
At Baseline (n=547,144,121,20,30)	13			
Baseline-CR; Month 6-CR (n=169,83,55,9,13)	9			
Baseline-CR; Month 6-MD (n=169,83,55,9,13)	2			
Baseline-CR; Month 6-Mod D (n=169,83,55,9,13)	1			
Baseline-CR; Month 6-SD (n=169,83,55,9,13)	0			
Baseline-CR; Month 6-Missing (n=169,83,55,9,13)	1			
Baseline-CR; Month 12-CR (n=169,83,55,9,13)	8			
Baseline-CR; Month 12-MD (n=169,83,55,9,13)	4			
Baseline-CR; Month 12-Mod D (n=169,83,55,9,13)	1			
Baseline-CR; Month 12-SD (n=169,83,55,9,13)	0			
Baseline-CR; Month 12-Missing (n=169,83,55,9,13)	0			

Baseline-CR; Month 18-CR (n=169,83,55,9,13)	9			
Baseline-CR; Month 18-MD (n=169,83,55,9,13)	0			
Baseline-CR; Month 18-Mod D (n=169,83,55,9,13)	3			
Baseline-CR; Month 18-SD (n=169,83,55,9,13)	0			
Baseline-CR; Month 18-Missing (n=169,83,55,9,13)	1			
Baseline-CR; Month 24-CR (n=169,83,55,9,13)	6			
Baseline-CR; Month 24-MD (n=169,83,55,9,13)	0			
Baseline-CR; Month 24-Mod D (n=169,83,55,9,13)	0			
Baseline-CR; Month 24-SD (n=169,83,55,9,13)	0			
Baseline-CR; Month 24-Missing (n=169,83,55,9,13)	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Disease Activity

End point title	Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Disease Activity

End point description:

Mayo Score: instrument to measure disease activity of UC. Score ranges: 0-12 points. There are 4 sub scores: graded from 0-3. Higher scores: more severe disease. Partial Mayo Score (PMS) (Mayo score without endoscopy) is comprised of 3 parameters: stool frequency from 0 (normal number of stools) to 3 (having >=5 stools more than normal), the presence of rectal bleeding (0=no blood seen to 3=blood alone passes), and physician's global assessment (0=normal to 3=severe disease). Total PMS: sum of all parameters, score from 0 (normal or inactive disease) to 9 (severe disease). Score was calculated if data was available for at least 1 of 3 sub scores. Level of disease activity: clinical remission (CR) (PMS <2), mild disease (MD) (PMS=2-4), moderate disease (Mod D) (PMS=5-6) and severe disease (SD) (PMS >6). FAS was analysed. "Number of Subjects Analysed" = number of subjects evaluable for this end point; "number analysed" = subjects evaluable at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	547	144	121	20
Units: Subjects				
At Baseline: MD (n=547,144,121,20,30)	157	30	28	4
At Baseline: Mod D (n=547,144,121,20,30)	76	13	9	3
At Baseline: SD (n=547,144,121,20,30)	47	5	3	0

Baseline-MD; Month 6-CR (n=157,30,28,4,9)	71	12	19	3
Baseline-MD; Month 6-MD (n=157,30,28,4,9)	48	12	4	1
Baseline-MD; Month 6-Mod D (n=157,30,28,4,9)	18	2	1	0
Baseline-MD; Month 6-SD (n=157,30,28,4,9)	7	0	1	0
Baseline-MD; Month 6-Missing (n=157,30,28,4,9)	13	4	3	0
Baseline-Mod D; Month 6-CR (n=76,13,9,3,4)	18	3	2	3
Baseline-Mod D; Month 6-MD (n=76,13,9,3,4)	22	8	5	0
Baseline-Mod D; Month 6-Mod D (n=76,13,9,3,4)	21	0	1	0
Baseline-Mod D; Month 6-SD (n=76,13,9,3,4)	8	1	0	0
Baseline-Mod D; Month 6-Missing (n=76,13,9,3,4)	7	1	1	0
Baseline-SD; Month 6-CR (n=47,5,3,0,1)	8	2	0	0
Baseline-SD; Month 6-MD (n=47,5,3,0,1)	19	1	1	0
Baseline-SD; Month 6-Mod D (n=47,5,3,0,1)	6	0	1	0
Baseline-SD; Month 6-SD (n=47,5,3,0,1)	7	0	1	0
Baseline-SD; Month 6-Missing (n=47,5,3,0,1)	7	2	0	0
Baseline-MD; Month 12-CR (n=157,30,28,4,9)	73	16	14	2
Baseline-MD; Month 12-MD (n=157,30,28,4,9)	38	6	7	1
Baseline-MD; Month 12-Mod D (n=157,30,28,4,9)	10	3	1	0
Baseline-MD; Month 12-SD (n=157,30,28,4,9)	3	0	1	1
Baseline-MD; Month 12-Missing (n=157,30,28,4,9)	33	5	5	0
Baseline-Mod D; Month 12-CR (n=76,13,9,3,4)	24	2	4	2
Baseline-Mod D; Month 12-MD (n=76,13,9,3,4)	17	6	2	0
Baseline-Mod D; Month 12-Mod D (n=76,13,9,3,4)	6	1	0	0
Baseline-Mod D; Month 12-SD (n=76,13,9,3,4)	2	0	0	0
Baseline-Mod D; Month 12-Missing (n=76,13,9,3,4)	27	4	3	1
Baseline-SD; Month 12-CR (n=47,5,3,0,1)	15	2	0	0
Baseline-SD; Month 12-MD (n=47,5,3,0,1)	8	1	1	0
Baseline-SD; Month 12-Mod D (n=47,5,3,0,1)	5	0	2	0
Baseline-SD; Month 12-SD (n=47,5,3,0,1)	2	0	0	0
Baseline-SD; Month 12-Missing (n=47,5,3,0,1)	17	2	0	0
Baseline-MD; Month 18-CR (n=157,30,28,4,9)	57	14	15	3

Baseline-MD; Month 18-MD (n=157,30,28,4,9)	22	5	6	0
Baseline-MD; Month 18-Mod D (n=157,30,28,4,9)	8	1	1	0
Baseline-MD; Month 18-SD (n=157,30,28,4,9)	2	0	0	0
Baseline-MD; Month 18-Missing (n=157,30,28,4,9)	68	10	6	1
Baseline-Mod D; Month 18-CR (n=76,13,9,3,4)	23	4	2	1
Baseline-Mod D; Month 18-MD (n=76,13,9,3,4)	16	2	1	0
Baseline-Mod D; Month 18-Mod D (n=76,13,9,3,4)	2	1	1	0
Baseline-Mod D; Month 18-SD (n=76,13,9,3,4)	0	0	0	0
Baseline-Mod D; Month 18-Missing (n=76,13,9,3,4)	35	6	5	2
Baseline-SD; Month 18-CR (n=47,5,3,0,1)	15	2	1	0
Baseline-SD; Month 18-MD (n=47,5,3,0,1)	5	1	2	0
Baseline-SD; Month 18-Mod D (n=47,5,3,0,1)	3	0	0	0
Baseline-SD; Month 18-SD (n=47,5,3,0,1)	0	0	0	0
Baseline-SD; Month 18-Missing (n=47,5,3,0,1)	24	2	0	0
Baseline-MD; Month 24-CR (n=157,30,28,4,9)	43	13	13	2
Baseline-MD; Month 24-MD (n=157,30,28,4,9)	10	4	3	0
Baseline-MD; Month 24-Mod D (n=157,30,28,4,9)	5	1	1	0
Baseline-MD; Month 24-SD (n=157,30,28,4,9)	0	0	0	0
Baseline-MD; Month 24-Missing (n=157,30,28,4,9)	99	12	11	2
Baseline-Mod D; Month 24-CR (n=76,13,9,3,4)	15	2	0	0
Baseline-Mod D; Month 24-MD (n=76,13,9,3,4)	11	3	0	0
Baseline-Mod D; Month 24-Mod D (n=76,13,9,3,4)	1	0	1	0
Baseline-Mod D; Month 24-SD (n=76,13,9,3,4)	2	1	1	0
Baseline-Mod D; Month 24-Missing (n=76,13,9,3,4)	47	7	7	3
Baseline-SD; Month 24-CR (n=47,5,3,0,1)	8	2	0	0
Baseline-SD; Month 24-MD (n=47,5,3,0,1)	8	1	1	0
Baseline-SD; Month 24-Mod D (n=47,5,3,0,1)	1	0	0	0
Baseline-SD; Month 24-SD (n=47,5,3,0,1)	0	0	0	0
Baseline-SD; Month 24-Missing (n=47,5,3,0,1)	30	2	2	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Subjects				
At Baseline: MD (n=547,144,121,20,30)	9			
At Baseline: Mod D (n=547,144,121,20,30)	4			
At Baseline: SD (n=547,144,121,20,30)	1			
Baseline-MD; Month 6-CR (n=157,30,28,4,9)	3			
Baseline-MD; Month 6-MD (n=157,30,28,4,9)	6			
Baseline-MD; Month 6-Mod D (n=157,30,28,4,9)	0			
Baseline-MD; Month 6-SD (n=157,30,28,4,9)	0			
Baseline-MD; Month 6-Missing (n=157,30,28,4,9)	0			
Baseline-Mod D; Month 6-CR (n=76,13,9,3,4)	2			
Baseline-Mod D; Month 6-MD (n=76,13,9,3,4)	2			
Baseline-Mod D; Month 6-Mod D (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 6-SD (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 6-Missing (n=76,13,9,3,4)	0			
Baseline-SD; Month 6-CR (n=47,5,3,0,1)	1			
Baseline-SD; Month 6-MD (n=47,5,3,0,1)	0			
Baseline-SD; Month 6-Mod D (n=47,5,3,0,1)	0			
Baseline-SD; Month 6-SD (n=47,5,3,0,1)	0			
Baseline-SD; Month 6-Missing (n=47,5,3,0,1)	0			
Baseline-MD; Month 12-CR (n=157,30,28,4,9)	2			
Baseline-MD; Month 12-MD (n=157,30,28,4,9)	5			
Baseline-MD; Month 12-Mod D (n=157,30,28,4,9)	1			
Baseline-MD; Month 12-SD (n=157,30,28,4,9)	0			
Baseline-MD; Month 12-Missing (n=157,30,28,4,9)	1			
Baseline-Mod D; Month 12-CR (n=76,13,9,3,4)	1			
Baseline-Mod D; Month 12-MD (n=76,13,9,3,4)	2			
Baseline-Mod D; Month 12-Mod D (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 12-SD (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 12-Missing (n=76,13,9,3,4)	1			
Baseline-SD; Month 12-CR (n=47,5,3,0,1)	1			

Baseline-SD; Month 12-MD (n=47,5,3,0,1)	0			
Baseline-SD; Month 12-Mod D (n=47,5,3,0,1)	0			
Baseline-SD; Month 12-SD (n=47,5,3,0,1)	0			
Baseline-SD; Month 12-Missing (n=47,5,3,0,1)	0			
Baseline-MD; Month 18-CR (n=157,30,28,4,9)	3			
Baseline-MD; Month 18-MD (n=157,30,28,4,9)	2			
Baseline-MD; Month 18-Mod D (n=157,30,28,4,9)	1			
Baseline-MD; Month 18-SD (n=157,30,28,4,9)	0			
Baseline-MD; Month 18-Missing (n=157,30,28,4,9)	3			
Baseline-Mod D; Month 18-CR (n=76,13,9,3,4)	1			
Baseline-Mod D; Month 18-MD (n=76,13,9,3,4)	2			
Baseline-Mod D; Month 18-Mod D (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 18-SD (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 18-Missing (n=76,13,9,3,4)	1			
Baseline-SD; Month 18-CR (n=47,5,3,0,1)	1			
Baseline-SD; Month 18-MD (n=47,5,3,0,1)	0			
Baseline-SD; Month 18-Mod D (n=47,5,3,0,1)	0			
Baseline-SD; Month 18-SD (n=47,5,3,0,1)	0			
Baseline-SD; Month 18-Missing (n=47,5,3,0,1)	0			
Baseline-MD; Month 24-CR (n=157,30,28,4,9)	5			
Baseline-MD; Month 24-MD (n=157,30,28,4,9)	1			
Baseline-MD; Month 24-Mod D (n=157,30,28,4,9)	0			
Baseline-MD; Month 24-SD (n=157,30,28,4,9)	0			
Baseline-MD; Month 24-Missing (n=157,30,28,4,9)	3			
Baseline-Mod D; Month 24-CR (n=76,13,9,3,4)	2			
Baseline-Mod D; Month 24-MD (n=76,13,9,3,4)	1			
Baseline-Mod D; Month 24-Mod D (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 24-SD (n=76,13,9,3,4)	0			
Baseline-Mod D; Month 24-Missing (n=76,13,9,3,4)	1			
Baseline-SD; Month 24-CR (n=47,5,3,0,1)	0			
Baseline-SD; Month 24-MD (n=47,5,3,0,1)	0			

Baseline-SD; Month 24-Mod D (n=47,5,3,0,1)	0			
Baseline-SD; Month 24-SD (n=47,5,3,0,1)	0			
Baseline-SD; Month 24-Missing (n=47,5,3,0,1)	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Age at Diagnosis

End point title	Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Age at Diagnosis

End point description:

The Montreal classification index for CD was used to classify the extent of the disease activity. It consisted of three parameters: age at diagnosis, location and behavior of the disease activity. There were four different age groups categorized: 16 years or younger, 17-40 years, over 40 years and missing. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, ''Overall number of subjects analysed'' =Number of subjects evaluable for this outcome measure and number analysed =subjects evaluable at specified rows for each arm.

End point type	Secondary

End point timeframe:

At Baseline

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	777	240	164	37
Units: Subjects				
16 years or younger	61	33	21	4
17-40 years	553	174	115	25
Over 40 years	162	33	28	8
Missing	1	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: Subjects				
16 years or younger	6			
17-40 years	39			
Over 40 years	5			
Missing	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Location

End point title	Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Location

End point description:

The Montreal classification index for CD was used to classify the extent of the disease activity. It consisted of three parameters: age at diagnosis, location and behavior of the disease activity. There are four different disease locations presented: Location 1 (L1) is terminal ileum (TI), Location 2 (L2) is colon, Location 3 (L3) is ileocolon (IC) and Location 4 (L4) is upper gastrointestinal (UGI). The first three categories (L1-L3) was combined with L4 where disease sites coexisted. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, ''Overall number of subjects analysed'' =Number of subjects evaluable for this outcome measure and number analysed= subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	969	348	237	47
Units: Subjects				
Baseline: Location L1 TI (n=777,240,164,37,50)	257	62	34	6
Month 6: Location L1 TI (n=589,202,127,33,44)	202	49	26	7
Month 12: Location L1 TI (n=468,160,104,33,40)	150	38	22	7
Month 18: Location L1 TI (n=330,124,85,22,36)	99	28	16	2
Month 24: Location L1 TI (n=190,75,57,18,27)	60	17	15	0
Baseline: Location L2 Colon (n=777,240,164,37,50)	135	54	32	14
Month 6: Location L2 Colon (n=589,202,127,33,44)	105	47	25	12
Month 12: Location L2 Colon (n=468,160,104,33,40)	84	40	20	14
Month 18: Location L2 Colon (n=330,124,85,22,36)	53	31	18	10
Month 24: Location L2 Colon (n=190,75,57,18,27)	41	16	14	9
Baseline: Location L3 IC (n=777,240,164,37,50)	329	107	80	16

Month 6: Location L3 IC (n=589,202,127,33,44)	236	94	65	13
Month 12: Location L3 IC (n=468,160,104,33,40)	200	71	55	11
Month 18: Location L3 IC (n=330,124,85,22,36)	150	55	40	8
Month 24: Location L3 IC (n=190,75,57,18,27)	74	33	22	9
Baseline: L4 UGI (n=777,240,164,37,50)	14	4	4	1
Month 6: L4 UGI (n=589,202,127,33,44)	12	2	3	1
Month 12: L4 UGI (n=468,160,104,33,40)	10	3	2	1
Month 18: L4 UGI (n=330,124,85,22,36)	8	5	4	1
Month 24: L4 UGI (n=190,75,57,18,27)	7	6	3	0
Baseline: L1 TI,L4 UGI (n=777,240,164,37,50)	21	2	1	0
Month 6: L1 TI, L4 UGI (n=589,202,127,33,44)	15	2	1	0
Month 12: L1 TI,L4 UGI (n=468,160,104,33,40)	11	2	1	0
Month 18: L1 TI,L4 UGI (n=330,124,85,22,36)	13	0	0	0
Month 24: L1 TI,L4 UGI (n=190,75,57,18,27)	2	0	0	0
Baseline: L2 Colon,L4 UGI (n=777,240,164,37,50)	6	2	1	0
Month 6: L2 Colon,L4 UGI (n=589,202,127,33,44)	3	3	0	0
Month 12: L2 Colon,L4 UGI (n=468,160,104,33,40)	2	1	0	0
Month 18: L2 Colon,L4 UGI (n=330,124,85,22,36)	2	1	0	0
Month 24: L2 Colon,L4 UGI (n=190,75,57,18,27)	0	1	0	0
Baseline: L3 IC, L4 UGI (n=777,240,164,37,50)	14	8	12	0
Month 6: L3 IC,L4 UGI (n=589,202,127,33,44)	11	5	7	0
Month 12: L3 IC, L4 UGI (n=468,160,104,33,40)	8	5	4	0
Month 18: L3 IC,L4 UGI (n=330,124,85,22,36)	5	4	7	1
Month 24: L3 IC,L4 UGI (n=190,75,57,18,27)	5	2	3	0
Baseline: Location Missing (n=777,240,164,37,50)	1	1	0	0
Month 6: Location Missing (n=589,202,127,33,44)	5	0	0	0
Month 12: Location Missing (n=468,160,104,33,40)	3	0	0	0
Month 18: Location Missing (n=330,124,85,22,36)	0	0	0	0
Month 24: Location Missing (n=190,75,57,18,27)	1	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: Subjects				
Baseline: Location L1 TI (n=777,240,164,37,50)	11			
Month 6: Location L1 TI (n=589,202,127,33,44)	9			
Month 12: Location L1 TI (n=468,160,104,33,40)	7			
Month 18: Location L1 TI (n=330,124,85,22,36)	8			
Month 24: Location L1 TI (n=190,75,57,18,27)	5			
Baseline: Location L2 Colon (n=777,240,164,37,50)	8			
Month 6: Location L2 Colon (n=589,202,127,33,44)	11			
Month 12: Location L2 Colon (n=468,160,104,33,40)	10			
Month 18: Location L2 Colon (n=330,124,85,22,36)	9			
Month 24: Location L2 Colon (n=190,75,57,18,27)	5			
Baseline: Location L3 IC (n=777,240,164,37,50)	28			
Month 6: Location L3 IC (n=589,202,127,33,44)	22			
Month 12: Location L3 IC (n=468,160,104,33,40)	21			
Month 18: Location L3 IC (n=330,124,85,22,36)	17			
Month 24: Location L3 IC (n=190,75,57,18,27)	14			
Baseline: L4 UGI (n=777,240,164,37,50)	0			
Month 6: L4 UGI (n=589,202,127,33,44)	0			
Month 12: L4 UGI (n=468,160,104,33,40)	1			
Month 18: L4 UGI (n=330,124,85,22,36)	1			
Month 24: L4 UGI (n=190,75,57,18,27)	1			
Baseline: L1 TI,L4 UGI (n=777,240,164,37,50)	1			
Month 6: L1 TI, L4 UGI (n=589,202,127,33,44)	0			
Month 12: L1 TI,L4 UGI (n=468,160,104,33,40)	0			
Month 18: L1 TI,L4 UGI (n=330,124,85,22,36)	0			
Month 24: L1 TI,L4 UGI (n=190,75,57,18,27)	0			
Baseline: L2 Colon,L4 UGI (n=777,240,164,37,50)	1			
Month 6: L2 Colon,L4 UGI (n=589,202,127,33,44)	0			
Month 12: L2 Colon,L4 UGI (n=468,160,104,33,40)	0			

Month 18: L2 Colon,L4 UGI (n=330,124,85,22,36)	0			
Month 24: L2 Colon,L4 UGI (n=190,75,57,18,27)	0			
Baseline: L3 IC, L4 UGI (n=777,240,164,37,50)	1			
Month 6: L3 IC,L4 UGI (n=589,202,127,33,44)	2			
Month 12: L3 IC, L4 UGI (n=468,160,104,33,40)	1			
Month 18: L3 IC,L4 UGI (n=330,124,85,22,36)	1			
Month 24: L3 IC,L4 UGI (n=190,75,57,18,27)	2			
Baseline: Location Missing (n=777,240,164,37,50)	0			
Month 6: Location Missing (n=589,202,127,33,44)	0			
Month 12: Location Missing (n=468,160,104,33,40)	0			
Month 18: Location Missing (n=330,124,85,22,36)	0			
Month 24: Location Missing (n=190,75,57,18,27)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Behavior of the Disease Activity

End point title	Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Behavior of the Disease Activity

End point description:

The Montreal classification index for CD was used to classify the extent of the disease activity. It consists of two parameters: location and behavior of the disease activity. There were 4 different categories for the behavior of the disease activity: Behaviour 1 (B1) was nonstricturing (NS), nonpenetrating (NP); Behaviour 2 (B2) was structuring (s); Behaviour 3 (B3) was penetrating (P) and p as perianal disease (p). The first 3 categories (B1 to B3) could be added with p to indicate coexisting perianal disease. Perianal disease (p) was defined as the presence of perianal abscesses or fistulae. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this end point. Number analysed= subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	969	348	237	47
Units: Subjects				
At Baseline: B1 NS, NP (n=777,240,164,37,50)	324	92	66	9
Month 6: B1 NS, NP (n=589,202,127,33,44)	242	68	46	10
Month 12: B1 NS, NP (n=468,160,104,33,40)	191	56	40	10
Month 18: B1 NS, NP (n=330,124,85,22,36)	135	44	26	4
Month 24: B1 NS, NP (n=190,75,57,18,27)	77	35	20	3
At Baseline: B2 Stricturing (n=777,240,164,37,50)	165	40	43	9
Month 6:B2 Stricturing (n=589,202,127,33,44)	122	29	36	8
Month 12: B2 Stricturing (n=468,160,104,33,40)	94	26	28	6
Month 18: B2 Stricturing (n=330,124,85,22,36)	77	24	26	4
Month 24: B2 Stricturing (n=190,75,57,18,27)	47	8	15	3
At Baseline: B3 Penetrating (n=777,240,164,37,50)	84	32	16	6
Month 6: B3 Penetrating (n=589,202,127,33,44)	64	32	14	5
Month 12: B3 Penetrating (n=468,160,104,33,40)	48	26	12	5
Month 18:B3 Penetrating (n=330,124,85,22,36)	26	16	9	4
Month 24: B3 Penetrating (n=190,75,57,18,27)	18	8	4	4
Baseline: Behavior p (n=777,240,164,37,50)	34	5	7	2
Month 6: Behavior p (n=589,202,127,33,44)	27	5	4	1
Month 12: Behavior p (n=468,160,104,33,40)	17	7	1	1
Month 18: Behavior p (n=330,124,85,22,36)	10	4	1	1
Month 24: Behavior p (n=190,75,57,18,27)	4	3	1	1
Baseline:B2 s, B3 Penetrating(n=777,240,164,37,50)	1	0	0	0
Month 6:B2 s, B3 Penetrating(n=589,202,127,33,44)	0	0	0	0
Month 12:B2 s, B3 Penetrating(n=468,160,104,33,40)	0	0	0	0
Month 18:B2 s, B3 Penetrating(n=330,124,85,22,36)	1	0	0	0
Month 24: B2 s, B3 Penetrating(n=190,75,57,18,27)	0	0	0	0
Baseline: B1 NS,NP, p (n=777,240,164,37,50)	77	33	16	5
Month 6: B1 NS,NP, p (n=589,202,127,33,44)	64	34	11	5
Month 12: B1 NS,NP, p (n=468,160,104,33,40)	60	20	9	6

Month 18: B1 NS,NP, p (n=330,124,85,22,36)	40	15	11	5
Month 24: B1 NS,NP, p (n=190,75,57,18,27)	23	8	6	5
At Baseline: B2 s, p (n=777,240,164,37,50)	32	8	4	1
Month 6: B2 s, p (n=589,202,127,33,44)	22	5	3	1
Month 12: B2 s, p (n=468,160,104,33,40)	22	5	3	2
Month 18: B2 s, p (n=330,124,85,22,36)	14	1	1	0
Month 24: B2 s, p (n=190,75,57,18,27)	5	1	1	0
Baseline: B2 s, B3 P, p (n=777,240,164,37,50)	0	0	0	0
Month 6: B2 s, B3 P, p (n=589,202,127,33,44)	1	0	0	0
Month 12: B2 s, B3 P, p (n=468,160,104,33,40)	0	0	0	0
Month 18: B2 s, B3 P, p (n=330,124,85,22,36)	0	0	0	0
Month 24: B2 s, B3 P, p (n=190,75,57,18,27)	0	0	0	0
At Baseline: B3 P, p (n=777,240,164,37,50)	57	30	12	5
Month 6: B3 P, p (n=589,202,127,33,44)	42	29	13	3
Month 12: Behavior B3 P, p (n=468,160,104,33,40)	33	20	11	3
Month 18: B3 P, p (n=330,124,85,22,36)	27	20	11	4
Month 24: B3 P, p (n=190,75,57,18,27)	15	12	10	2
Baseline: Behavior Missing (n=777,240,164,37,50)	3	0	0	0
Month 6: Behavior Missing (n=589,202,127,33,44)	5	0	0	0
Month 12: Behavior Missing (n=468,160,104,33,40)	3	0	0	0
Month 18: Behavior Missing (n=330,124,85,22,36)	0	0	0	0
Month 24: Behavior Missing (n=190,75,57,18,27)	1	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: Subjects				
At Baseline: B1 NS, NP (n=777,240,164,37,50)	17			
Month 6: B1 NS, NP (n=589,202,127,33,44)	14			
Month 12: B1 NS, NP (n=468,160,104,33,40)	17			
Month 18: B1 NS, NP (n=330,124,85,22,36)	13			
Month 24: B1 NS, NP (n=190,75,57,18,27)	7			

At Baseline: B2 Stricturing (n=777,240,164,37,50)	13			
Month 6:B2 Stricturing (n=589,202,127,33,44)	12			
Month 12: B2 Stricturing (n=468,160,104,33,40)	9			
Month 18: B2 Stricturing (n=330,124,85,22,36)	10			
Month 24: B2 Stricturing (n=190,75,57,18,27)	9			
At Baseline: B3 Penetrating (n=777,240,164,37,50)	6			
Month 6: B3 Penetrating (n=589,202,127,33,44)	5			
Month 12: B3 Penetrating (n=468,160,104,33,40)	2			
Month 18:B3 Penetrating (n=330,124,85,22,36)	2			
Month 24: B3 Penetrating (n=190,75,57,18,27)	2			
Baseline: Behavior p (n=777,240,164,37,50)	3			
Month 6: Behavior p (n=589,202,127,33,44)	1			
Month 12: Behavior p (n=468,160,104,33,40)	1			
Month 18: Behavior p (n=330,124,85,22,36)	0			
Month 24: Behavior p (n=190,75,57,18,27)	0			
Baseline:B2 s, B3 Penetrating(n=777,240,164,37,50)	0			
Month 6:B2 s, B3 Penetrating(n=589,202,127,33,44)	0			
Month 12:B2 s, B3 Penetrating(n=468,160,104,33,40)	0			
Month 18:B2 s, B3 Penetrating(n=330,124,85,22,36)	0			
Month 24: B2 s, B3 Penetrating(n=190,75,57,18,27)	0			
Baseline: B1 NS,NP, p (n=777,240,164,37,50)	5			
Month 6: B1 NS,NP, p (n=589,202,127,33,44)	6			
Month 12: B1 NS,NP, p (n=468,160,104,33,40)	6			
Month 18: B1 NS,NP, p (n=330,124,85,22,36)	6			
Month 24: B1 NS,NP, p (n=190,75,57,18,27)	5			
At Baseline: B2 s, p (n=777,240,164,37,50)	1			
Month 6: B2 s, p (n=589,202,127,33,44)	0			
Month 12: B2 s, p (n=468,160,104,33,40)	0			
Month 18: B2 s, p (n=330,124,85,22,36)	0			
Month 24: B2 s, p (n=190,75,57,18,27)	0			
Baseline: B2 s, B3 P, p (n=777,240,164,37,50)	0			

Month 6: B2 s, B3 P, p (n=589,202,127,33,44)	0			
Month 12: B2 s, B3 P, p (n=468,160,104,33,40)	0			
Month 18: B2 s, B3 P, p (n=330,124,85,22,36)	0			
Month 24: B2 s, B3 P, p (n=190,75,57,18,27)	0			
At Baseline: B3 P, p (n=777,240,164,37,50)	5			
Month 6: B3 P, p (n=589,202,127,33,44)	6			
Month 12: Behavior B3 P, p (n=468,160,104,33,40)	5			
Month 18: B3 P, p (n=330,124,85,22,36)	5			
Month 24: B3 P, p (n=190,75,57,18,27)	4			
Baseline: Behavior Missing (n=777,240,164,37,50)	0			
Month 6: Behavior Missing (n=589,202,127,33,44)	0			
Month 12: Behavior Missing (n=468,160,104,33,40)	0			
Month 18: Behavior Missing (n=330,124,85,22,36)	0			
Month 24: Behavior Missing (n=190,75,57,18,27)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Extent

End point title	Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Extent

End point description:

The Montreal classification index for Ulcerative Colitis (UC) was used to classify the extent and severity of the disease activity. There were three subgroups of UC defined by extent: Extent 1 (E1) =Ulcerative Proctitis (UP), Extent 2 (E2) =Left-sided UC and Extent 3 (E3) =Extensive UC. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this outcome measure. Number analysed= subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	547	144	121	20
Units: Subjects				
Baseline E1 UP (n=380,86,66,16,22)	41	10	5	0
Month 6 E1 UP (n=302,72,50,15,20)	31	9	1	0
Month 12 E1 UP (n=224,66,38,14,18)	17	7	4	0
Month 18 E1 UP (n=168,53,32,8,17)	15	7	2	0
Month 24 E1 UP (n=101,30,25,5,11)	14	5	2	0
Baseline E2 Left-sided UC (n=380,86,66,16,22)	151	26	30	3
Month 6 E2 Left-sided UC (n=302,72,50,15,20)	109	23	24	3
Month 12 E2 Left-sided UC (n=224,66,38,14,18)	76	21	13	3
Month 18 E2 Left-sided UC (n=168,53,32,8,17)	55	16	12	1
Month 24 E2 Left-sided UC (n=101,30,25,5,11)	26	10	8	1
Baseline E3 Extensive UC (n=380,86,66,16,22)	188	50	31	13
Month 6 E3 Extensive UC (n=302,72,50,15,20)	159	40	25	12
Month 12 E3 Extensive UC (n=224,66,38,14,18)	128	37	21	11
Month 18 E3 Extensive UC (n=168,53,32,8,17)	96	29	18	7
Month 24 E3 Extensive UC (n=101,30,25,5,11)	59	15	15	4
Baseline Missing (n=380,86,66,16,22)	0	0	0	0
Month 6 Missing (n=302,72,50,15,20)	3	0	0	0
Month 12 Missing (n=224,66,38,14,18)	3	1	0	0
Month 18 Missing (n=168,53,32,8,17)	2	1	0	0
Month 24 Missing (n=101,30,25,5,11)	2	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Subjects				
Baseline E1 UP (n=380,86,66,16,22)	2			
Month 6 E1 UP (n=302,72,50,15,20)	1			
Month 12 E1 UP (n=224,66,38,14,18)	1			
Month 18 E1 UP (n=168,53,32,8,17)	2			
Month 24 E1 UP (n=101,30,25,5,11)	0			
Baseline E2 Left-sided UC (n=380,86,66,16,22)	8			
Month 6 E2 Left-sided UC (n=302,72,50,15,20)	6			
Month 12 E2 Left-sided UC (n=224,66,38,14,18)	7			
Month 18 E2 Left-sided UC (n=168,53,32,8,17)	5			

Month 24 E2 Left-sided UC (n=101,30,25,5,11)	2			
Baseline E3 Extensive UC (n=380,86,66,16,22)	12			
Month 6 E3 Extensive UC (n=302,72,50,15,20)	13			
Month 12 E3 Extensive UC (n=224,66,38,14,18)	10			
Month 18 E3 Extensive UC (n=168,53,32,8,17)	10			
Month 24 E3 Extensive UC (n=101,30,25,5,11)	9			
Baseline Missing (n=380,86,66,16,22)	0			
Month 6 Missing (n=302,72,50,15,20)	0			
Month 12 Missing (n=224,66,38,14,18)	0			
Month 18 Missing (n=168,53,32,8,17)	0			
Month 24 Missing (n=101,30,25,5,11)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Severity

End point title	Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Severity

End point description:

The Montreal classification index for UC was used to classify the extent and severity of the disease activity. UC can be classified broadly into four disease activity/severity categories: Severity 0 (S0) = asymptomatic clinical remission; Severity 1 (S1) = Mild UC (passage of four or fewer stools/day [with or without blood], absence of any systemic illness, and normal inflammatory markers); Severity 2 (S2) = Moderate UC (passage of more than four stools per day but with minimal signs of systemic toxicity) and Severity 3 (S3) = Severe UC (passage of at least six bloody stools daily). FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this outcome measure. Number analysed =subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	547	144	121	20
Units: Subjects				
Baseline S0 (n=380,86,66,16,22)	80	46	24	6
Month 6 S0 (n=302,72,50,15,20)	122	40	26	9
Month 12 S0 (n=224,66,38,14,18)	110	39	25	10
Month 18 S0 (168,53,32,8,17)	81	35	23	6
Month 24 S0 (n=101,30,25,5,11)	71	20	17	3
Baseline S1 (n=380,86,66,16,22)	75	17	18	6

Month 6 S1 (n=302,72,50,15,20)	70	19	15	3
Month 12 S1 (n=224,66,38,14,18)	58	16	5	1
Month 18 S1 (168,53,32,8,17)	41	11	5	0
Month 24 S1 (n=101,30,25,5,11)	12	6	5	1
Baseline S2 (n=380,86,66,16,22)	147	14	19	3
Month 6 S2 (n=302,72,50,15,20)	74	7	6	3
Month 12 S2 (n=224,66,38,14,18)	40	6	5	2
Month 18 S2 (168,53,32,8,17)	29	5	2	2
Month 24 S2 (n=101,30,25,5,11)	12	3	1	1
Baseline S3 (n=380,86,66,16,22)	75	9	5	1
Month 6 S3 (n=302,72,50,15,20)	32	5	3	0
Month 12 S3 (n=224,66,38,14,18)	11	3	3	1
Month 18 S3 (168,53,32,8,17)	15	1	2	0
Month 24 S3 (n=101,30,25,5,11)	6	1	2	0
Baseline Missing (n=380,86,66,16,22)	3	0	0	0
Month 6 Missing (n=302,72,50,15,20)	4	1	0	0
Month 12 Missing (n=224,66,38,14,18)	5	2	0	0
Month 18 Missing (168,53,32,8,17)	2	1	0	0
Month 24 Missing (n=101,30,25,5,11)	0	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: Subjects				
Baseline S0 (n=380,86,66,16,22)	6			
Month 6 S0 (n=302,72,50,15,20)	7			
Month 12 S0 (n=224,66,38,14,18)	6			
Month 18 S0 (168,53,32,8,17)	8			
Month 24 S0 (n=101,30,25,5,11)	7			
Baseline S1 (n=380,86,66,16,22)	4			
Month 6 S1 (n=302,72,50,15,20)	9			
Month 12 S1 (n=224,66,38,14,18)	8			
Month 18 S1 (168,53,32,8,17)	4			
Month 24 S1 (n=101,30,25,5,11)	2			
Baseline S2 (n=380,86,66,16,22)	9			
Month 6 S2 (n=302,72,50,15,20)	3			
Month 12 S2 (n=224,66,38,14,18)	4			
Month 18 S2 (168,53,32,8,17)	4			
Month 24 S2 (n=101,30,25,5,11)	2			
Baseline S3 (n=380,86,66,16,22)	3			
Month 6 S3 (n=302,72,50,15,20)	1			
Month 12 S3 (n=224,66,38,14,18)	0			
Month 18 S3 (168,53,32,8,17)	1			
Month 24 S3 (n=101,30,25,5,11)	0			
Baseline Missing (n=380,86,66,16,22)	0			
Month 6 Missing (n=302,72,50,15,20)	0			
Month 12 Missing (n=224,66,38,14,18)	0			
Month 18 Missing (168,53,32,8,17)	0			

Month 24 Missing (n=101,30,25,5,11)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Fistula Drainage Assessment Index

End point title	Crohn's Disease: Number of Subjects Categorised on the Basis of Fistula Drainage Assessment Index

End point description:

The fistula drainage assessment index was used to assess the improvement or remission of the disease activity of Crohn's Disease, based on 6 categories: remission (remission was defined as closure of all fistulae that were draining at baseline for at least two consecutive visits); improvement (improvement defined as a decrease from baseline in the number of open draining fistulae of 50% for at least two consecutive visits); worsened; unchanged; not accessible and missing disease activity. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this end point. Number analysed= subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	969	348	237	47
Units: Subjects				
Baseline: Remission (n=191,58,22,16,12)	64	30	14	3
Month 6: Remission (n=169,58,26,16,14)	65	29	17	6
Month 12:Remission (n=121,39,17,14,11)	50	23	11	9
Month 18: Remission (n=79,26,14,12,10)	36	16	9	6
Month 24: Remission (n=38,21,12,11,10)	16	12	4	7
Baseline: Improvement (n=191,58,22,16,12)	90	26	5	11
Month 6: Improvement (n=169,58,26,16,14)	62	23	3	9
Month 12: Improvement (n=121,39,17,14,11)	39	8	3	1
Month 18: Improvement (n=79,26,14,12,10)	23	4	1	2
Month 24: Improvement (n=38,21,12,11,10)	8	6	3	3
Baseline: Worsened (n=191,58,22,16,12)	9	0	0	0

Month 6: Worsened (n=169,58,26,16,14)	12	1	3	1
Month 12: Worsened (n=121,39,17,14,11)	9	0	0	1
Month 18: Worsened (n=79,26,14,12,10)	5	1	0	2
Month 24: Worsened (n=38,21,12,11,10)	3	0	2	0
Baseline: Unchanged (n=191,58,22,16,12)	19	2	3	2
Month 6: Unchanged (n=169,58,26,16,14)	21	5	3	0
Month 12: Unchanged (n=121,39,17,14,11)	20	8	3	3
Month 18: Unchanged (n=79,26,14,12,10)	15	5	3	2
Month 24: Unchanged (n=38,21,12,11,10)	8	3	3	1
Baseline: Not accessible (n=191,58,22,16,12)	4	0	0	0
Month 6: Not accessible (n=169,58,26,16,14)	4	0	0	0
Month 12: Not accessible (n=121,39,17,14,11)	1	0	0	0
Month 18: Not accessible (n=79,26,14,12,10)	0	0	1	0
Month 24: Not accessible (n=38,21,12,11,10)	1	0	0	0
Baseline: Missing (n=191,58,22,16,12)	5	0	0	0
Month 6: Missing (n=169,58,26,16,14)	5	0	0	0
Month 12: Missing (n=121,39,17,14,11)	2	0	0	0
Month 18: Missing (n=79,26,14,12,10)	0	0	0	0
Month 24: Missing (n=38,21,12,11,10)	2	0	0	0

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	72			
Units: Subjects				
Baseline: Remission (n=191,58,22,16,12)	6			
Month 6: Remission (n=169,58,26,16,14)	8			
Month 12:Remission (n=121,39,17,14,11)	9			
Month 18: Remission (n=79,26,14,12,10)	8			
Month 24: Remission (n=38,21,12,11,10)	7			
Baseline: Improvement (n=191,58,22,16,12)	4			
Month 6: Improvement (n=169,58,26,16,14)	4			
Month 12: Improvement (n=121,39,17,14,11)	0			
Month 18: Improvement (n=79,26,14,12,10)	0			

Month 24: Improvement (n=38,21,12,11,10)	1			
Baseline: Worsened (n=191,58,22,16,12)	0			
Month 6: Worsened (n=169,58,26,16,14)	0			
Month 12: Worsened (n=121,39,17,14,11)	0			
Month 18: Worsened (n=79,26,14,12,10)	0			
Month 24: Worsened (n=38,21,12,11,10)	0			
Baseline: Unchanged (n=191,58,22,16,12)	1			
Month 6: Unchanged (n=169,58,26,16,14)	2			
Month 12: Unchanged (n=121,39,17,14,11)	2			
Month 18: Unchanged (n=79,26,14,12,10)	2			
Month 24: Unchanged (n=38,21,12,11,10)	2			
Baseline: Not accessible (n=191,58,22,16,12)	1			
Month 6: Not accessible (n=169,58,26,16,14)	0			
Month 12: Not accessible (n=121,39,17,14,11)	0			
Month 18: Not accessible (n=79,26,14,12,10)	0			
Month 24: Not accessible (n=38,21,12,11,10)	0			
Baseline: Missing (n=191,58,22,16,12)	0			
Month 6: Missing (n=169,58,26,16,14)	0			
Month 12: Missing (n=121,39,17,14,11)	0			
Month 18: Missing (n=79,26,14,12,10)	0			
Month 24: Missing (n=38,21,12,11,10)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Laboratory Test Results: C-Reactive Protein at Months 6, 12, 18, and 24

End point title	Mean Change From Baseline in Laboratory Test Results: C-Reactive Protein at Months 6, 12, 18, and 24

End point description:

C-reactive protein (CRP) was a laboratory measurement for evaluation of an acute phase reactant of inflammation through the use of an ultra-sensitive assay. A decrease in the level of CRP indicated reduction in inflammation and therefore improvement. FAS=all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to treatment or assessment of CD or UC). Here, Number analysed= subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Months 6, 12, 18 and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1516	492	358	67
Units: milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (n=1044,330,229,49,67)	13.70 (± 43.8)	10.23 (± 22.6)	8.79 (± 17.0)	7.70 (± 11.8)
Change at Month 6 (n=933,285,216,45,66)	-1.09 (± 47.4)	1.46 (± 40.0)	-1.45 (± 14.6)	-1.88 (± 12.3)
Change at Month 12 (n=678,243,166,38,55)	-4.87 (± 38.6)	-2.23 (± 17.3)	-1.62 (± 12.2)	3.88 (± 25.4)
Change at Month 18 (n=428,174,122,27,48)	-6.57 (± 45.2)	0.63 (± 37.7)	-2.45 (± 11.7)	1.83 (± 12.6)
Change at Month 24 (234,131,94,21,32)	0.33 (± 177.3)	-3.51 (± 18.2)	3.19 (± 41.7)	4.17 (± 24.6)

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (n=1044,330,229,49,67)	12.18 (± 30.7)			
Change at Month 6 (n=933,285,216,45,66)	0.94 (± 32.8)			
Change at Month 12 (n=678,243,166,38,55)	-4.84 (± 30.7)			
Change at Month 18 (n=428,174,122,27,48)	-0.59 (± 51.8)			
Change at Month 24 (234,131,94,21,32)	-3.11 (± 19.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Laboratory Test Results: Fecal Calprotectin at Months 6, 12, 18, and 24

End point title	Mean Change From Baseline in Laboratory Test Results: Fecal Calprotectin at Months 6, 12, 18, and 24

End point description:

Here, the laboratory tests related to the treatment or assessment of Crohn's Disease or Ulcerative Colitis was fecal calprotectin. FAS=all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to treatment or assessment of CD or UC). Here, Number analysed= subjects evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:
Baseline, Months 6, 12, 18, and 24

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1516	492	358	67
Units: milligram per kilogram (mg/kg)				
arithmetic mean (standard deviation)				
Baseline (n=202,47,35,8,16)	1066.31 (± 5419.8)	556.88 (± 916.2)	362.48 (± 642.8)	616.03 (± 1023.3)
Change at Month 6 (n=107,28,12,5,8)	-283.21 (± 989.0)	-296.95 (± 958.1)	-164.60 (± 440.8)	-648.16 (± 1333.1)
Change at Month 12 (n=55,22,10,2,7)	-165.32 (± 691.9)	361.51 (± 1741.1)	-289.57 (± 1004.9)	-382.73 (± 503.1)
Change at Month 18 (n=48,12,9,4,5)	-473.07 (± 1394.3)	275.48 (± 1518.0)	88.44 (± 746.8)	-73.94 (± 125.3)
Change at Month 24 (n=22,5,6,2,2)	-625.69 (± 1684.7)	-862.40 (± 958.4)	-494.66 (± 1226.4)	-13.35 (± 273.4)

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: milligram per kilogram (mg/kg)				
arithmetic mean (standard deviation)				
Baseline (n=202,47,35,8,16)	537.58 (± 1471.9)			
Change at Month 6 (n=107,28,12,5,8)	224.56 (± 700.1)			
Change at Month 12 (n=55,22,10,2,7)	-643.67 (± 2339.3)			
Change at Month 18 (n=48,12,9,4,5)	109.16 (± 164.4)			
Change at Month 24 (n=22,5,6,2,2)	-450.98 (± 200.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Imaging Test Results

End point title	Number of Subjects With Imaging Test Results

End point description:

Number of subjects who had Imaging test results related to the treatment or assessment of Crohn's Disease or Ulcerative Colitis were reported. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to treatment or assessment of CD or UC).

End point type	Secondary

End point timeframe:

From baseline up to follow-up period (a maximum of 2 years)

End point values	CT-P13	Remicade	Switched From Remicade to CT-P13	Switched From CT-P13 to Remicade
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1516	492	358	67
Units: Subjects	516	134	106	28

End point values	Multiple Switchers			
Subject group type	Reporting group			
Number of subjects analysed	102			
Units: Subjects	50			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline to follow-up period (up to a maximum duration of 2 years)

Adverse event reporting additional description:

Same event may appear as both an adverse event (AE) and serious adverse event (SAE). However, what is presented are distinct events. An event may be categorized as serious in 1 subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event. Safety population was evaluated.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Remicade

Reporting group description:

Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months.

Reporting group title	CT-P13

Reporting group description:

Subjects diagnosed with either Crohn’s Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months.

Reporting group title	Switched From CT-P13 to Remicade

Reporting group description:

Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months.

Reporting group title	Multiple Switchers

Reporting group description:

Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD.

Reporting group title	Switched From Remicade to CT-P13

Reporting group description:

Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months.

Serious adverse events	Remicade	CT-P13	Switched From CT-P13 to Remicade
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 494 (8.70%)	256 / 1522 (16.82%)	10 / 67 (14.93%)
number of deaths (all causes)	2	4	0
number of deaths resulting from adverse events	0	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer in situ			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			

subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seminoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aneurysm			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Behcet's syndrome			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poor venous access			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Caesarean section			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colectomy			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventriculo-peritoneal shunt			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	3 / 494 (0.61%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal death			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adhesion			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site extravasation			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Condition aggravated			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug ineffective			
subjects affected / exposed	1 / 494 (0.20%)	11 / 1522 (0.72%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 1	5 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Paradoxical drug reaction			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenosis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			

subjects affected / exposed	0 / 494 (0.00%)	5 / 1522 (0.33%)	2 / 67 (2.99%)
occurrences causally related to treatment / all	0 / 0	6 / 6	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type I hypersensitivity			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervix carcinoma			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrocystic breast disease			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gynaecomastia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst torsion			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Alveolitis allergic			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 494 (0.00%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory symptom			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
C-reactive protein increased			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CSF pressure			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug specific antibody present			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anastomotic fistula			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic ulcer haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			

subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maternal exposure during pregnancy			
subjects affected / exposed	3 / 494 (0.61%)	5 / 1522 (0.33%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with aura			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphopenia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 494 (0.00%)	11 / 1522 (0.72%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 494 (0.00%)	7 / 1522 (0.46%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 494 (0.00%)	13 / 1522 (0.85%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	4 / 15	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	3 / 494 (0.61%)	13 / 1522 (0.85%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 3	5 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	5 / 494 (1.01%)	23 / 1522 (1.51%)	2 / 67 (2.99%)
occurrences causally related to treatment / all	1 / 5	3 / 27	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 494 (0.00%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous fistula			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of small intestine			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal anastomotic stenosis			
subjects affected / exposed	1 / 494 (0.20%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal perforation			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal stenosis			
subjects affected / exposed	1 / 494 (0.20%)	11 / 1522 (0.72%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory bowel disease			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	2 / 494 (0.40%)	5 / 1522 (0.33%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal stenosis			
subjects affected / exposed	2 / 494 (0.40%)	8 / 1522 (0.53%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	1 / 494 (0.20%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malabsorption			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 494 (0.20%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal stenosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 494 (0.00%)	8 / 1522 (0.53%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis sclerosing			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	2 / 494 (0.40%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular injury			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus hepatitis			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Cutaneous vasculitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hidradenitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palmoplantar pustulosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustular psoriasis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin reaction			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder disorder			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney congestion			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			

subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocorticotropic hormone deficiency			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Angiomyolipoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankylosing spondylitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthralgia			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis enteropathic			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			

subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcopenia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 494 (0.00%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	1 / 494 (0.20%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 494 (0.20%)	5 / 1522 (0.33%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula infection			

subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			

subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 494 (0.00%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptosporidiosis infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection			

subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 494 (0.40%)	1 / 1522 (0.07%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			

subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 494 (0.00%)	9 / 1522 (0.59%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural sepsis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 494 (0.20%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Skin infection			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Multiple Switchers	Switched From Remicade to CT-P13	
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 102 (14.71%)	57 / 358 (15.92%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer in situ			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seminoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Behcet's syndrome			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery embolism			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poor venous access			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Caesarean section			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventriculo-peritoneal shunt			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 102 (0.98%)	2 / 358 (0.56%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal death			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adhesion			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Administration site extravasation			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Condition aggravated			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug ineffective			
subjects affected / exposed	0 / 102 (0.00%)	5 / 358 (1.40%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face oedema			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paradoxical drug reaction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type I hypersensitivity			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cervix carcinoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrocystic breast disease			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst torsion			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Alveolitis allergic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory symptom			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric decompensation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
C-reactive protein increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CSF pressure			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug specific antibody present			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Anastomotic fistula			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Anastomotic ulcer haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Maternal exposure during pregnancy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Cerebral infarction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine with aura			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicytopenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphopenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 102 (0.00%)	3 / 358 (0.84%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 102 (0.98%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	0 / 102 (0.00%)	6 / 358 (1.68%)	
occurrences causally related to treatment / all	0 / 0	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous fistula			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula of small intestine			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal anastomotic stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal perforation			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal stenosis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory bowel disease			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal stenosis			
subjects affected / exposed	1 / 102 (0.98%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malabsorption			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer perforation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis sclerosing			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis cholestatic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lupus hepatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Cutaneous vasculitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis psoriasiform			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hidradenitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palmoplantar pustulosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pustular psoriasis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma gangrenosum			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin reaction			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder disorder			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IgA nephropathy			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney congestion			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenocorticotropic hormone deficiency			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steroid withdrawal syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Angiomyolipoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankylosing spondylitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis enteropathic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcopenia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess intestinal			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 102 (0.00%)	3 / 358 (0.84%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic tonsillitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptosporidiosis infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus colitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated tuberculosis			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epstein-Barr virus infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 102 (0.98%)	2 / 358 (0.56%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected fistula			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Measles			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Remicade	CT-P13	Switched From CT-P13 to Remicade
Total subjects affected by non-serious adverse events			
subjects affected / exposed	100 / 494 (20.24%)	442 / 1522 (29.04%)	7 / 67 (10.45%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Malignant melanoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Malignant melanoma in situ			

subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Malignant melanoma stage III			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Skin cancer			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Poor venous access			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Intestinal resection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 494 (0.20%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	1	3	0
Gestational trophoblastic detachment			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Drug ineffective			
subjects affected / exposed	24 / 494 (4.86%)	187 / 1522 (12.29%)	0 / 67 (0.00%)
occurrences (all)	24	187	0

Dysplasia			
subjects affected / exposed	2 / 494 (0.40%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	1 / 494 (0.20%)	5 / 1522 (0.33%)	0 / 67 (0.00%)
occurrences (all)	1	5	0
Feeling abnormal			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Fibrosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
General physical health deterioration			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	1 / 67 (1.49%)
occurrences (all)	1	1	1
Unevaluable event			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Hypersensitivity			

subjects affected / exposed	10 / 494 (2.02%)	29 / 1522 (1.91%)	0 / 67 (0.00%)
occurrences (all)	10	32	0
Serum sickness			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Type I hypersensitivity			
subjects affected / exposed	2 / 494 (0.40%)	9 / 1522 (0.59%)	0 / 67 (0.00%)
occurrences (all)	2	9	0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Lung disorder			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Respiratory distress			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 494 (0.40%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	2	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Blood count abnormal			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
C-reactive protein increased			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Colonoscopy			

subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Drug specific antibody present			
subjects affected / exposed	1 / 494 (0.20%)	6 / 1522 (0.39%)	0 / 67 (0.00%)
occurrences (all)	1	6	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Mean cell volume decreased			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Exposure to communicable disease			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	3 / 494 (0.61%)	24 / 1522 (1.58%)	0 / 67 (0.00%)
occurrences (all)	4	24	0
Limb injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Maternal exposure during pregnancy			
subjects affected / exposed	13 / 494 (2.63%)	34 / 1522 (2.23%)	0 / 67 (0.00%)
occurrences (all)	14	37	0
Medication error			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Suture related complication			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Wound dehiscence			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Angina pectoris			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Demyelination			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Meningioma			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Demyelinating polyneuropathy			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 494 (0.81%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	5	1	0
Iron deficiency anaemia			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Lymphadenopathy			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Neurosensory hypoacusis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Retinal vein occlusion			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Scleritis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 494 (0.20%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	1	3	0
Abdominal tenderness			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Colitis			

subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Colitis ulcerative			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Crohn's disease			
subjects affected / exposed	0 / 494 (0.00%)	7 / 1522 (0.46%)	0 / 67 (0.00%)
occurrences (all)	0	8	0
Diarrhoea			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Enteritis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal anastomotic stenosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Ileal stenosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hiatus hernia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Intestinal stenosis			
subjects affected / exposed	3 / 494 (0.61%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	3	3	0
Large intestinal stenosis			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	2	0	0
Obstruction gastric			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Pancreatic failure			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Pancreatitis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Pouchitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Subileus			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Toothache			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Cholelithiasis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0

Cholestasis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hepatic steatosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hepatocellular injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Actinic keratosis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	1 / 494 (0.20%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	1	2	0
Blister			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Drug eruption			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Erythema			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Erythema nodosum			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Hidradenitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Prurigo			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Pruritus generalised			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	3 / 494 (0.61%)	11 / 1522 (0.72%)	0 / 67 (0.00%)
occurrences (all)	3	11	0
Rash			
subjects affected / exposed	1 / 494 (0.20%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	1	4	0
Rash erythematous			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Rebound psoriasis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin reaction			
subjects affected / exposed	1 / 494 (0.20%)	18 / 1522 (1.18%)	0 / 67 (0.00%)
occurrences (all)	2	19	0
Skin ulcer			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Thyroiditis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	11 / 494 (2.23%)	12 / 1522 (0.79%)	0 / 67 (0.00%)
occurrences (all)	11	12	0
Arthritis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Arthropathy			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Lupus-like syndrome			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Osteonecrosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Anal abscess			
subjects affected / exposed	2 / 494 (0.40%)	5 / 1522 (0.33%)	0 / 67 (0.00%)
occurrences (all)	2	5	0
Anal fistula infection			

subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	2 / 494 (0.40%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	2	3	0
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Cellulitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Erysipelas			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Folliculitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			

subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis viral			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Genital herpes			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Genital herpes zoster			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Groin abscess			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Herpes virus infection			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 494 (0.00%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences (all)	0	4	0
Hordeolum			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Impetigo			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Infection			

subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Laryngitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Latent tuberculosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	1 / 67 (1.49%)
occurrences (all)	0	2	1
Nail infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	3 / 494 (0.61%)	5 / 1522 (0.33%)	0 / 67 (0.00%)
occurrences (all)	4	5	0
Onychomycosis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Ophthalmic herpes simplex			
subjects affected / exposed	0 / 494 (0.00%)	3 / 1522 (0.20%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Opportunistic infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Oral fungal infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Oral herpes			

subjects affected / exposed	1 / 494 (0.20%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences (all)	1	4	0
Otitis media acute			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Papilloma viral infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Pertussis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 494 (0.00%)	2 / 1522 (0.13%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Pyelonephritis			
subjects affected / exposed	0 / 494 (0.00%)	4 / 1522 (0.26%)	0 / 67 (0.00%)
occurrences (all)	0	4	0
Respiratory tract infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 494 (0.20%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Skin infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			

subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Tinea versicolour			
subjects affected / exposed	1 / 494 (0.20%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Ureteritis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	1 / 494 (0.20%)	3 / 1522 (0.20%)	1 / 67 (1.49%)
occurrences (all)	1	3	1
Varicella zoster virus infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Vulval abscess			
subjects affected / exposed	0 / 494 (0.00%)	0 / 1522 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			

Cell death			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 494 (0.00%)	1 / 1522 (0.07%)	0 / 67 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Multiple Switchers	Switched From Remicade to CT-P13	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 102 (20.59%)	90 / 358 (25.14%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Malignant melanoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Malignant melanoma in situ			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Malignant melanoma stage III			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Skin cancer			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	

Poor venous access			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Intestinal resection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Gestational trophoblastic detachment			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Drug ineffective			
subjects affected / exposed	9 / 102 (8.82%)	23 / 358 (6.42%)	
occurrences (all)	9	23	
Dysplasia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 102 (0.00%)	4 / 358 (1.12%)	
occurrences (all)	0	5	
Feeling abnormal			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Fibrosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
General physical health deterioration			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	

Influenza like illness			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Unevaluable event			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Hypersensitivity			
subjects affected / exposed	1 / 102 (0.98%)	4 / 358 (1.12%)	
occurrences (all)	1	5	
Serum sickness			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Type I hypersensitivity			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			

Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Haemoptysis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Lung disorder			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Nasal discomfort			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Respiratory distress			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Depressed mood			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Insomnia			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Blood count abnormal			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Colonoscopy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Drug specific antibody present			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Mean cell volume decreased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Exposure to communicable disease			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			

subjects affected / exposed	0 / 102 (0.00%)	3 / 358 (0.84%)	
occurrences (all)	0	5	
Limb injury			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Maternal exposure during pregnancy			
subjects affected / exposed	1 / 102 (0.98%)	9 / 358 (2.51%)	
occurrences (all)	1	9	
Medication error			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Suture related complication			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Wound			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Wound dehiscence			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Angina pectoris			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Cardiovascular insufficiency			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Nervous system disorders			
Demyelination			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Dizziness			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Facial paralysis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Meningioma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Demyelinating polyneuropathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Neurosensory hypoacusis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Retinal vein occlusion			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Scleritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences (all)	0	2	
Abdominal tenderness			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Anal fistula			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Colitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Colitis ulcerative			
subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences (all)	0	4	
Crohn's disease			
subjects affected / exposed	0 / 102 (0.00%)	3 / 358 (0.84%)	
occurrences (all)	0	3	
Diarrhoea			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Enteritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal anastomotic stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	

Gastrointestinal pain			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Ileal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hiatus hernia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Intestinal obstruction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Intestinal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Large intestinal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Obstruction gastric			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Oesophagitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pancreatic failure			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pancreatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	

Pouchitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Subileus			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Cholelithiasis			
subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences (all)	0	2	
Cholestasis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hepatic steatosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Hepatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hepatocellular injury			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Non-alcoholic steatohepatitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			

Acne			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Actinic keratosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Blister			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Dermatitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Dermatitis allergic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Dermatitis psoriasiform			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Drug eruption			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Dyshidrotic eczema			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	

Erythema			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Erythema nodosum			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Hidradenitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Ingrowing nail			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Prurigo			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pruritus generalised			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Psoriasis			
subjects affected / exposed	0 / 102 (0.00%)	3 / 358 (0.84%)	
occurrences (all)	0	4	
Rash			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Rash erythematous			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Rebound psoriasis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Skin lesion			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	

Skin reaction			
subjects affected / exposed	3 / 102 (2.94%)	4 / 358 (1.12%)	
occurrences (all)	3	4	
Skin ulcer			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Thyroiditis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Arthritis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Arthropathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Lupus-like syndrome			
subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences (all)	0	2	
Musculoskeletal discomfort			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	

Osteonecrosis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Systemic lupus erythematosus			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Anal abscess			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Anal fistula infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	1 / 102 (0.98%)	2 / 358 (0.56%)	
occurrences (all)	1	3	
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Clostridium difficile infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			

subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Cystitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Ear infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Erysipelas			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Folliculitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Fungal infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Gastrointestinal infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Genital herpes			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Genital herpes zoster			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Gingivitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Groin abscess			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Herpes virus infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 102 (0.00%)	3 / 358 (0.84%)	
occurrences (all)	0	3	
Hordeolum			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Impetigo			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Laryngitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Latent tuberculosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Nail infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			

subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences (all)	0	2	
Onychomycosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Ophthalmic herpes simplex			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Opportunistic infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	2	
Oral candidiasis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Oral fungal infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Otitis media acute			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Papilloma viral infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Parvovirus B19 infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Periodontitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pertussis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pneumonia			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Pyelonephritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Rhinitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Subcutaneous abscess			
subjects affected / exposed	1 / 102 (0.98%)	0 / 358 (0.00%)	
occurrences (all)	1	0	
Tinea cruris			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Tinea pedis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Tinea versicolour			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Tooth abscess			
subjects affected / exposed	0 / 102 (0.00%)	2 / 358 (0.56%)	
occurrences (all)	0	2	
Ureteritis			

subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Varicella zoster virus infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Vulval abscess			
subjects affected / exposed	0 / 102 (0.00%)	1 / 358 (0.28%)	
occurrences (all)	0	1	
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Cell death			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Iron deficiency			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 102 (0.00%)	0 / 358 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported