Clinical trial results:
A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter study to Evaluate the Safety and Efficacy of Ustekinumab Induction and MaintenanceTherapy in Subjects with Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2014-005606-38
Trial protocol	DE HU AT CZ DK NL SK BE BG PL IT
Global end of trial date	30 November 2021

Results information

Result version number	v1
This version publication date	16 December 2022
First version publication date	16 December 2022

Trial information

Trial identification

Sponsor protocol code	CNTO1275UCO3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02407236
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 US Highway 202, Raritan, NJ, United States, 08869-1420
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.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	30 November 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 November 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the efficacy and safety of ustekinumab as intravenous (IV: intothe vein) infusion in induction study in subjects with moderately to severely active Ulcerative Colitis (UC) andas subcutaneous (SC) administration in maintenance study in subjects with moderately to severely activeUlcerative Colitis (UC) who have demonstrated a clinical response to Induction treatment with IV ustekinumab.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 July 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 26
Country: Number of subjects enrolled	Austria: 4
Country: Number of subjects enrolled	Belgium: 39
Country: Number of subjects enrolled	Bulgaria: 21
Country: Number of subjects enrolled	Canada: 16
Country: Number of subjects enrolled	Czechia: 30
Country: Number of subjects enrolled	Germany: 45
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	France: 54
Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	Hungary: 39
Country: Number of subjects enrolled	Israel: 6
Country: Number of subjects enrolled	Italy: 33
Country: Number of subjects enrolled	Japan: 107
Country: Number of subjects enrolled	Korea, Republic of: 26
Country: Number of subjects enrolled	Netherlands: 16
Country: Number of subjects enrolled	New Zealand: 19
Country: Number of subjects enrolled	Poland: 71

Country: Number of subjects enrolled	Romania: 24
Country: Number of subjects enrolled	Russian Federation: 74
Country: Number of subjects enrolled	Serbia: 10
Country: Number of subjects enrolled	Slovakia: 10
Country: Number of subjects enrolled	Ukraine: 89
Country: Number of subjects enrolled	United States: 179
Worldwide total number of subjects	961
EEA total number of subjects	388

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)	910
From 65 to 84 years	51
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 961 subjects enrolled in the Induction study. Out of 961 subjects, 783 subjects were further enrolled in the Maintenance study, out of which 588 subjects were furthur enter the Long-term extension study.

Period 1

Period 1 title	Induction Study (8 weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Induction Study(IS): Placebo Intravenous (IV)

Arm description:

Subjects received single dose of placebo as intravenous (IV) infusion at Week 0. Participants with clinical response at Week (W) 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received weight-range based dose of ustekinumab approximating 6 mg/kg IV + placebo SC at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Placebo was administered as an IV infusion.

Arm title	IS: Ustekinumab 130 milligram (mg) IV

Arm description:

Subjects received single dose of ustekinumab 130 mg as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 130 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Ustekinumab 130 mg was administered as an IV infusion.

Arm title	IS: Ustekinumab approximately 6mg/kg IV

Arm description:

Subjects received weight-range based dose of ustekinumab approximating 6 milligram per kilogram (mg/kg) (ustekinumab 260 mg [body weight <=55 kg], 390 mg [body weight >55 kg <=85 kg] and 520 mg [body weight >85 kg]), as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 6 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Ustekinumab 6 mg/kg was administered as an IV infusion.

Number of subjects in period 1	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV
Started	319	320	322
Completed	296	309	307
Not completed	23	11	15
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	17	9	7
Physician decision	1	1	-
Adverse event, non-fatal	3	-	1
Unspecified	2	1	5
Lack of efficacy	-	-	1

Period 2

Period 2 title	Maintenance Study (44 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Maintenance study(MS): Placebo Subcutaneous (SC)

Arm description:

Subjects in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab who were randomized to receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was administered as SC infusion.

Arm title	MS: Ustekinumab 90mg SC every 12 weeks (q12w)

Arm description:

Subjects who were randomized to receive ustekinumab (ie, 130 mg IV or approximately 6 mg/kg IV) at Week 0 of the induction study and were in clinical response at induction Week 8 and subjects who were randomized to receive placebo at Week 0 of the induction study and were not in clinical response at induction Week 8 but were in clinical response at induction Week 16 after receiving a dose of IV ustekinumab (approximately 6 mg/kg) at induction Week 8 (placebo to ustekinumab 6 mg/kg IV) were randomized to receive ustekinumab 90 mg SC every 12 weeks (q12w) beginning at Week 0 of maintenance study through Week 44.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Ustekinumab 90 mg was administered as SC infusion every 12 weeks.

Arm title	MS: Ustekinumab 90mg SC every 8 weeks (q8w)

Arm description:

Subjects who were randomized to receive ustekinumab (ie, 130 mg IV or approximately 6 mg/kg IV) at Week 0 of the induction study and were in clinical response at induction Week 8 and subjects who were randomized to receive placebo at Week 0 of the induction study and were not in clinical response at induction Week 8 but were in clinical response at induction Week 16 after receiving a dose of IV ustekinumab (approximately 6 mg/kg) at induction Week 8 (placebo to ustekinumab 6 mg/kg IV) were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w), beginning at Week 0 of maintenance study through Week 44.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Ustekinumab 90 mg was administered as SC infusion every 8 weeks.

Arm title	MS: Placebo IV (IS – Responders) to Placebo SC

Arm description:

Subjects with clinical response to Induction Week 0 treatment with placebo IV received placebo SC, beginning at Week 0 of maintenance study through Week 44 (non-randomized subjects).

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was administered as SC infusion (Responders who received Placebo IV during IS).

Arm title	MS: Ustekinumab Delayed Responders(IS) to UST 90mg SC q8w

Arm description:

Subjects who were delayed responders to ustekinumab induction (were not in clinical response to induction treatment ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 but were in clinical response at Week 16, after receiving ustekinumab 90 mg SC at Week 8) received ustekinumab 90 mg SC every 8 weeks, beginning at Week 0 of maintenance study through Week 44 (non-randomized subjects).

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Ustekinumab 90 mg was administered as SC infusion (delayed responders who received Ustekinumab during IS).

Number of subjects in period 2[1]	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)
Started	175	172	176
Completed	132	148	158
Not completed	43	24	18
Adverse event, serious fatal	-	-	-
Adverse event, non-fatal	19	8	4
Unspecified	5	7	8
Lack of efficacy	19	9	6

Number of subjects in period 2[1]	MS: Placebo IV (IS – Responders) to Placebo SC	MS: Ustekinumab Delayed Responders(IS) to UST 90mg SC q8w
Started	103	157
Completed	76	128
Not completed	27	29
Adverse event, serious fatal	-	1
Adverse event, non-fatal	11	10
Unspecified	4	6
Lack of efficacy	12	12

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Out of the 912 subjects who were enrolled in Induction study, only 783 subjects entered the Maintainance study and of which 588 subjects entered the LTE study.

Period 3

Period 3 title	Long-term Extension Study (176 weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Long Term Extension (LTE): Placebo SC

Arm description:

Subjects who were randomized to receive placebo SC in the maintenance study and received placebo SC at the first dosing visit (Week 48) of long term extension (LTE).

Arm type	Placebo
Investigational medicinal product name	Placebo SC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was continued as SC infusion in LTE phase

Arm title	LTE: Ustekinumab 90 mg SC q12w

Arm description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 12 weeks (q12w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Ustekinumab 90 mg was continued as SC infusion in LTE phase for subjects who were benefited from this during MS study, every 12 weeks.

Arm title	LTE: Ustekinumab 90 mg SC q8w

Arm description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Ustekinumab 90 mg was continued as SC infusion in LTE phase for subjects who were benefited from this during MS study, every 8 weeks.

Arm title	LTE: Placebo IV (IS – Responders) to Placebo SC

Arm description:

Subjects with clinical response to Induction Week 0 treatment with placebo IV received placebo SC in the maintenance study and the LTE through Week 200 (non-randomized subjects).

Arm type	Placebo
Investigational medicinal product name	Placebo SC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was continued SC in LTE phase for subjects who were benefited from this during MS study (Responders who received Placebo IV during MS study).

Arm title	LTE: Ustekinumab Delayed Responders (IS) to UST 90mg SC q8w

Arm description:

Subjects who were delayed responders to ustekinumab induction (were not in clinical response to induction treatment ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 but were in clinical response at Week 16, after receiving ustekinumab 90 mg SC at Week 8) received ustekinumab 90 mg SC q8w in the maintenance study and the LTE through Week 200 (non-randomized subjects).

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Ustekinumab 90 mg was administered as SC infusion (delayed responders who received Ustekinumab during MS) during LTE phase.

Number of subjects in period 3[2]	Long Term Extension (LTE): Placebo SC	LTE: Ustekinumab 90 mg SC q12w	LTE: Ustekinumab 90 mg SC q8w
Started	115	141	143
Completed	34	99	101
Not completed	81	42	42
Adverse event, non-fatal	9	17	10
Unspecified	63	19	19
Lost to follow-up	-	-	1
Lack of efficacy	9	6	12

Number of subjects in period 3[2]	LTE: Placebo IV (IS – Responders) to Placebo SC	LTE: Ustekinumab Delayed Responders (IS) to UST 90mg SC q8w
Started	73	116
Completed	0	95
Not completed	73	21
Adverse event, non-fatal	11	9
Unspecified	55	6

Lost to follow-up	-	-
Lack of efficacy	7	6

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Out of the 912 subjects who were enrolled in Induction study, only 783 subjects entered the Maintainance study and of which 588 subjects entered the LTE study.

Baseline characteristics

Reporting groups

Reporting group title	Induction Study(IS): Placebo Intravenous (IV)

Reporting group description:

Subjects received single dose of placebo as intravenous (IV) infusion at Week 0. Participants with clinical response at Week (W) 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received weight-range based dose of ustekinumab approximating 6 mg/kg IV + placebo SC at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Ustekinumab 130 milligram (mg) IV

Reporting group description:

Subjects received single dose of ustekinumab 130 mg as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Ustekinumab approximately 6mg/kg IV

Reporting group description:

Subjects received weight-range based dose of ustekinumab approximating 6 milligram per kilogram (mg/kg) (ustekinumab 260 mg [body weight <=55 kg], 390 mg [body weight >55 kg <=85 kg] and 520 mg [body weight >85 kg]), as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV
Number of subjects	319	320	322
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)	303	302	305
From 65-84 years	16	18	17
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	41.2	42.2	41.7
standard deviation	± 13.50	± 13.94	± 13.67

Sex: Female, Male Units: participants			
Female	122	130	127
Male	197	190	195
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	48	46	49
Black or African American	3	6	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	248	239	243
More than one race	0	0	0
Unknown or Not Reported	12	20	17
Other	8	9	12
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	10	7	7
Not Hispanic or Latino	292	295	290
Unknown or Not Reported	17	18	25
Region of enrollment Units: Subjects			
AUSTRALIA	7	8	11
AUSTRIA	0	2	2
BELGIUM	22	10	7
BULGARIA	8	9	4
CANADA	7	6	3
CZECH REPUBLIC	8	9	13
DENMARK	0	0	2
FRANCE	14	21	19
GERMANY	19	14	12
HUNGARY	11	12	16
ISRAEL	0	3	3
ITALY	10	11	12
JAPAN	34	34	39
NETHERLANDS	5	8	3
NEW ZEALAND	4	4	11
POLAND	25	26	20
ROMANIA	7	9	8
RUSSIAN FEDERATION	26	22	26
SERBIA	1	6	3
SLOVAKIA	4	4	2
SOUTH KOREA	10	10	6
UKRAINE	32	26	31
UNITED KINGDOM	5	3	13
UNITED STATES	60	63	56

Reporting group values	Total		
Number of subjects	961		

Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	910		
From 65-84 years	51		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: participants			
Female	379		
Male	582		
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1		
Asian	143		
Black or African American	9		
Native Hawaiian or Other Pacific Islander	0		
White	730		
More than one race	0		
Unknown or Not Reported	49		
Other	29		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	24		
Not Hispanic or Latino	877		
Unknown or Not Reported	60		
Region of enrollment Units: Subjects			
AUSTRALIA	26		
AUSTRIA	4		
BELGIUM	39		
BULGARIA	21		
CANADA	16		
CZECH REPUBLIC	30		
DENMARK	2		
FRANCE	54		
GERMANY	45		
HUNGARY	39		
ISRAEL	6		
ITALY	33		
JAPAN	107		

NETHERLANDS	16		
NEW ZEALAND	19		
POLAND	71		
ROMANIA	24		
RUSSIAN FEDERATION	74		
SERBIA	10		
SLOVAKIA	10		
SOUTH KOREA	26		
UKRAINE	89		
UNITED KINGDOM	21		
UNITED STATES	179		

End points

End points reporting groups

Reporting group title	Induction Study(IS): Placebo Intravenous (IV)

Reporting group description:

Subjects received single dose of placebo as intravenous (IV) infusion at Week 0. Participants with clinical response at Week (W) 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received weight-range based dose of ustekinumab approximating 6 mg/kg IV + placebo SC at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Ustekinumab 130 milligram (mg) IV

Reporting group description:

Subjects received single dose of ustekinumab 130 mg as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Ustekinumab approximately 6mg/kg IV

Reporting group description:

Subjects received weight-range based dose of ustekinumab approximating 6 milligram per kilogram (mg/kg) (ustekinumab 260 mg [body weight <=55 kg], 390 mg [body weight >55 kg <=85 kg] and 520 mg [body weight >85 kg]), as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	Maintenance study(MS): Placebo Subcutaneous (SC)

Reporting group description:

Subjects in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab who were randomized to receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44.

Reporting group title	MS: Ustekinumab 90mg SC every 12 weeks (q12w)

Reporting group description:

Subjects who were randomized to receive ustekinumab (ie, 130 mg IV or approximately 6 mg/kg IV) at Week 0 of the induction study and were in clinical response at induction Week 8 and subjects who were randomized to receive placebo at Week 0 of the induction study and were not in clinical response at induction Week 8 but were in clinical response at induction Week 16 after receiving a dose of IV ustekinumab (approximately 6 mg/kg) at induction Week 8 (placebo to ustekinumab 6 mg/kg IV) were randomized to receive ustekinumab 90 mg SC every 12 weeks (q12w) beginning at Week 0 of maintenance study through Week 44.

Reporting group title	MS: Ustekinumab 90mg SC every 8 weeks (q8w)

Reporting group description:

Subjects who were randomized to receive ustekinumab (ie, 130 mg IV or approximately 6 mg/kg IV) at Week 0 of the induction study and were in clinical response at induction Week 8 and subjects who were randomized to receive placebo at Week 0 of the induction study and were not in clinical response at induction Week 8 but were in clinical response at induction Week 16 after receiving a dose of IV ustekinumab (approximately 6 mg/kg) at induction Week 8 (placebo to ustekinumab 6 mg/kg IV) were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w), beginning at Week 0 of maintenance study through Week 44.

Reporting group title	MS: Placebo IV (IS – Responders) to Placebo SC

Reporting group description:

Subjects with clinical response to Induction Week 0 treatment with placebo IV received placebo SC, beginning at Week 0 of maintenance study through Week 44 (non-randomized subjects).

Reporting group title	MS: Ustekinumab Delayed Responders(IS) to UST 90mg SC q8w

Reporting group description:

Subjects who were delayed responders to ustekinumab induction (were not in clinical response to induction treatment ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 but were in clinical response at Week 16, after receiving ustekinumab 90 mg SC at Week 8) received ustekinumab 90 mg SC every 8 weeks, beginning at Week 0 of maintenance study through Week 44 (non-randomized subjects).

Reporting group title	Long Term Extension (LTE): Placebo SC

Reporting group description:

Subjects who were randomized to receive placebo SC in the maintenance study and received placebo SC at the first dosing visit (Week 48) of long term extension (LTE).

Reporting group title	LTE: Ustekinumab 90 mg SC q12w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 12 weeks (q12w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Reporting group title	LTE: Ustekinumab 90 mg SC q8w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Reporting group title	LTE: Placebo IV (IS – Responders) to Placebo SC

Reporting group description:

Subjects with clinical response to Induction Week 0 treatment with placebo IV received placebo SC in the maintenance study and the LTE through Week 200 (non-randomized subjects).

Reporting group title	LTE: Ustekinumab Delayed Responders (IS) to UST 90mg SC q8w

Reporting group description:

Subjects who were delayed responders to ustekinumab induction (were not in clinical response to induction treatment ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 but were in clinical response at Week 16, after receiving ustekinumab 90 mg SC at Week 8) received ustekinumab 90 mg SC q8w in the maintenance study and the LTE through Week 200 (non-randomized subjects).

Primary: Induction Study - Number of Subjects with Clinical Remission at Week 8 (As per Global Definition)

End point title	Induction Study - Number of Subjects with Clinical Remission at Week 8 (As per Global Definition)

End point description:

As per global definition, clinical remission is defined as a Mayo score less than or equal to (<=)2 points, with no individual subscore greater than (>)1. The Mayo score consists of 4 subscores (stool frequency, rectal bleeding [RB], endoscopy findings, and physician's global assessment [PGA]), rated as 0 (normal) to 3 (severe). Total score was calculated as the sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5 = mild; 6 to 10 = moderate; and 11 to 12 = severe; higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant ulcerative colitis (UC) medication or an ostomy or colectomy prior to the Week 8 or who had all 4 Mayo subscores missing at Week 8 were considered not to be in clinical remission. Endoscopy subscore as assessed during central review of video of endoscopy was used. The primary efficacy analysis set (PEAS) consisted of all subjects randomized in the induction study.

End point type	Primary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	17	50	50	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Study(IS): Placebo Intravenous (IV) v IS: Ustekinumab 130 milligram (mg) IV
Number of subjects included in analysis	639
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	10.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	14.9

Statistical analysis title	Statistical Analysis 2
Comparison groups	Induction Study(IS): Placebo Intravenous (IV) v IS: Ustekinumab approximately 6mg/kg IV
Number of subjects included in analysis	641
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.6
upper limit	14.8

Primary: Induction Study - Number of Subjects with Clinical Remission at Week 8 (As per US Definition)

End point title	Induction Study - Number of Subjects with Clinical Remission

	at Week 8 (As per US Definition)

End point description:

As per US definition, clinical remission was defined as absolute stool number <=3, a Mayo rectal bleeding subscore of 0 (no blood seen), and a Mayo endoscopy subscore of 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]) without the physician's global assessment. Absolute stool number is average of daily stool number over the three days. The Mayo rectal bleeding and endoscopy findings subscores were rated as 0 (normal) to 3 (severe). Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who were missing all 3 of the Mayo components pertaining to this outcome measure (OM) (absolute stool number, rectal bleeding subscore, and Mayo endoscopy subscore) at Week 8 were considered not to be in clinical remission. Endoscopy subscore as assessed during central review of the video of the endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Primary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	20	53	61	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Study(IS): Placebo Intravenous (IV) v IS: Ustekinumab 130 milligram (mg) IV
Number of subjects included in analysis	639
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	10.3
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	4.8
upper limit	15.8

Statistical analysis title	Statistical Analysis 2
Comparison groups	Induction Study(IS): Placebo Intravenous (IV) v IS: Ustekinumab approximately 6mg/kg IV

Number of subjects included in analysis	641
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	12.7
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	7
upper limit	18.4

Primary: Maintenance Study: Number of Subjects with Clinical Remission at Week 44 (As per Global Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission at Week 44 (As per Global Definition)

End point description:

As per global definition, clinical remission defined as Mayo score <=2 points with no individual subscore >1. It consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment) rated as 0 (normal) to 3 (severe). Total score is sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5=mild; 6 to 10=moderate; 11 to 12=severe; higher scores means worsening of UC. Subjects who had a prohibited change in UC medication or an ostomy or colectomy or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 or who had all 4 Mayo subscores missing at Week 44 were considered not to be in clinical remission. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Primary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	42	66	77	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance study(MS): Placebo Subcutaneous (SC) v MS: Ustekinumab 90mg SC every 8 weeks (q8w)

Number of subjects included in analysis	351
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	19.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.3
upper limit	29

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance study(MS): Placebo Subcutaneous (SC) v MS: Ustekinumab 90mg SC every 12 weeks (q12w)
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	14.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.5
upper limit	23.6

Primary: Maintenance Study: Number of Subjects with Clinical Remission at Week 44 (as per US Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission at Week 44 (as per US Definition)

End point description:

Per US definition, clinical remission: absolute stool number <=3, a Mayo rectal bleeding subscore of 0 (no blood seen) and Mayo endoscopy subscore of 0 (normal/inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]), without the physician's global assessment. Absolute stool number is average of daily stool number over 3 days. The Mayo rectal bleeding and endoscopy findings subscores were rated as 0 (normal)-3 (severe). Subjects who had prohibited change in UC medication/ ostomy/ colectomy/used rescue medication after clinical flare/discontinued study agent due to lack of therapeutic effect/due to AE of worsening of UC prior to Week 44 and who were missing all 3 of Mayo components at Week 44 were considered not to be in clinical remission. PEAS consisted of all subjects who were in clinical response to IV UST induction and were randomized at Week 0 of the maintenance study to UST 90 mg SC q8w, UST 90 mg SC q12w, or placebo SC.

End point type	Primary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	43	68	75	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance study(MS): Placebo Subcutaneous (SC) v MS: Ustekinumab 90mg SC every 8 weeks (q8w)
Number of subjects included in analysis	351
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	17.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.6
upper limit	27.2

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance study(MS): Placebo Subcutaneous (SC) v MS: Ustekinumab 90mg SC every 12 weeks (q12w)
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted treatment difference
Point estimate	15.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	6
upper limit	24.2

Secondary: Induction Study: Number of Subjects with Endoscopic Healing (EH) at Week 8

End point title	Induction Study: Number of Subjects with Endoscopic Healing (EH) at Week 8

End point description:

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It is defined as Mayo endoscopic subscore = 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]). Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who had a missing endoscopy score at Week 8 were considered not to have endoscopic healing. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	44	84	87	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: Number of Subjects with Clinical Response at Week 8

End point title	Induction Study: Number of Subjects with Clinical Response at Week 8

End point description:

Clinical response was defined as a decrease from induction baseline in the Mayo score by >=30 percent (%) and >= 3 points, with either a decrease from baseline in the rectal bleeding subscore >=1 or a rectal bleeding subscore of 0 or 1. The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Total score was calculated as the sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5 = mild; 6 to 10 = moderate; and 11 to 12 = severe; higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who had all 4 Mayo subscores missing at Week 8 were considered not to be in clinical response. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	100	164	199	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change From Baseline in Total Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 8

End point title	Induction Study - Change From Baseline in Total Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 8

End point description:

IBDQ is 32-item questionnaire used to evaluate disease-specific health-related quality of life. Each item score ranged from 1 (worst response) to 7 (best response). and were grouped into 4 domains: bowel function, emotional status, systemic symptoms and social function. These domains scored as: 10 to 70 (bowel symptoms); 5 to 35 (systemic symptoms); 12 to 84 (emotional function); and 5 to 35 (social function) and higher score means better quality of life. Total score is sum of each item score and ranges from 32\-224 with higher score means better quality of life. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from time of event onward or subjects who had missing IBDQ score at Week 8 had their last value carried forward. PEAS consisted of all subjects randomized in induction study. Here, N (number of subjects analyzed) signifies those subjects who were analyzed for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Units on a scale				
arithmetic mean (standard deviation)	16.1 (± 31.39)	33.4 (± 32.53)	35.0 (± 31.86)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Response up to Week 44

End point title	Maintenance Study: Number of Subjects with Clinical Response

	up to Week 44

End point description:

Clinical response: decrease from induction baseline in Mayo score by >= 30% and >= 3 points, with either decrease from induction baseline in rectal bleeding subscore >=1 or rectal bleeding subscore of 0 or 1. It includes 4 subscores (stool frequency, rectal bleeding, endoscopy findings, physician's global assessment), rated as 0 (normal) to 3 (severe). Higher scores indicate worsening of disease. Subjects who lost clinical response at any time before Week 44, had prohibited change in UC medication, ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 or who had all 4 Mayo subscores missing at Week 44 were considered not to be in clinical response. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	78	117	125	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Endoscopic Healing at Week 44

End point title	Maintenance Study: Number of Subjects with Endoscopic Healing at Week 44

End point description:

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It was defined as Mayo endoscopic subscore = 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]). Subjects who had prohibited change in UC medication, an ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC prior to Week 44 or who had missing endoscopy score at Week 44 were considered not to have endoscopic healing. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	50	75	90	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission and not Receiving Concomitant Corticosteroids (Corticosteroid-free Clinical Remission) at Week 44 (As per Global Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission and not Receiving Concomitant Corticosteroids (Corticosteroid-free Clinical Remission) at Week 44 (As per Global Definition)

End point description:

Per global definition, clinical remission was defined as Mayo score <=2 points, with no individual subscore >1. It consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Higher scores indicate worsening of disease. Subjects who had prohibited change in UC medication/ ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 or had all 4 Mayo subscores missing at Week 44 were considered not to have achieved OM of clinical remission and not receiving corticosteroids at Week 44. Subjects who had missing value in corticosteroid use at Week 44 had their last value carried forward. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w/ placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	41	65	74	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission and not Receiving Concomitant Corticosteroids (Corticosteroid-free Clinical Remission) at Week 44 (As per US Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission and not Receiving Concomitant Corticosteroids (Corticosteroid-free Clinical Remission) at Week 44 (As per US Definition)

End point description:

US definition of clinical remission: absolute stool number <=3, rectal bleeding subscore 0 (no blood seen), Mayo endoscopy subscore of 0(normal or inactive disease)/ 1 (mild disease). Mayo rectal bleeding and endoscopy findings subscores rated: 0 (normal) to 3 (severe). Subjects with prohibited change in UC medication/ostomy/colectomy/used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 or were missing all 3 of Mayo components (absolute stool number, rectal bleeding, and Mayo endoscopy subscore) at Week 44 were considered not in corticosteroid-free clinical remission at Week 44. Subjects with missing value in corticosteroid use at Week 44 had last value carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomised at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	42	67	72	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission up to Week 44 Among Participants who Achieved Clinical Remission at Maintenance Study Baseline (As per Global Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission up to Week 44 Among Participants who Achieved Clinical Remission at Maintenance Study Baseline (As per Global Definition)

End point description:

Global definition of clinical remission: Mayo score <=2 points, with no individual subscore >1. It includes 4 subscores (stool frequency, rectal bleeding, endoscopy findings, PGA), rated as 0 (normal) to 3 (severe). Total score: sum of 4 subscores and range: 0 to 12, where 3 to 5= mild, 6 to 10= moderate, and 11 to 12= severe; higher scores means worsening of disease. Subjects who had prohibited change in UC medication/ostomy/colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 or had all 4 subscores missing at Week 44 were considered not to be in clinical remission. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects who were in clinical remission at maintenance baseline.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	40	38	
Units: Subjects	17	26	22	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission up to Week 44 Among Subjects who Achieved Clinical Remission at Maintenance Study Baseline (As per US Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission up to Week 44 Among Subjects who Achieved Clinical Remission at Maintenance Study Baseline (As per US Definition)

End point description:

US definition of clinical remission: absolute stool number <=3, Mayo rectal bleeding subscore of 0 (no blood seen), Mayo endoscopy subscore of 0 (normal/ inactive disease) or 1 (mild disease). Absolute stool number: average of daily stool number over 3 days. Mayo rectal bleeding and endoscopy subscores: 0 (normal) to 3 (severe). Subjects with prohibited change in UC medication/ostomy/colectomy/used rescue medication after clinical flare/ discontinued study drug due to lack of therapeutic effect/ AE of worsening of UC before Week 44/ missing all 3 of Mayo components (absolute stool number, rectal bleeding, and Mayo endoscopy subscore) at Week 44 were considered not in clinical remission. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects who were in clinical remission at MS baseline.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	52	44	
Units: Subjects	16	32	27	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Mucosal Healing at Week 8

End point title	Induction Study - Number of Subjects with Mucosal Healing at Week 8

End point description:

Mucosal healing is defined as having both EH and histologic healing (HH). EH: an endoscopy subscore of 0 (normal or inactive disease) or 1 mild disease ([erythema, decreased vascular pattern, mild friability]). Histologic healing: neutrophil infiltration in <5% of crypts, no crypt destruction, and no erosions or ulcerations or granulation tissue. Subjects who had prohibited change in concomitant UC medication/ ostomy/ colectomy before Week 8 or had missing endoscopy score/ were missing any component of histologic healing (that is assessment of neutrophils in crypts, crypt destruction/ erosions/ ulcerations/ granulations) at Week 8 or who had unevaluable biopsy (that is biopsy collected, but could not be assessed due to sample preparation or technical errors) at Week 8 but who did not achieve endoscopic healing, were considered not to have mucosal healing. PEAS consisted of all subjects randomised in the IS, with subjects whose mucosal healing status was determined at Week 8.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	316	316	315	
Units: Subjects	64	28	58	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects in Clinical Remission with a Rectal Bleeding Subscore of 0 at Week 8 (As per Global Definition)

End point title	Induction Study - Number of Subjects in Clinical Remission with a Rectal Bleeding Subscore of 0 at Week 8 (As per Global Definition)

End point description:

As per global definition, clinical remission is defined as Mayo score <=2 points, with no individual subscore >1. The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Total score is calculated as sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5 = mild; 6 to 10 = moderate; and 11 to 12 = severe; higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 or who had missing rectal bleeding subscores at Week 8 were considered not to be in clinical remission with a rectal bleeding subscore of 0. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	17	49	49	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects in Symptomatic Remission at Week 8

End point title	Induction Study - Number of Subjects in Symptomatic Remission at Week 8

End point description:

Symptomatic remission was defined as a Mayo stool frequency subscore of 0 (normal number of stools) or 1 (1-2 stools more than normal) and a rectal bleeding subscore of 0 (no blood seen). Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 and/or both stool frequency and rectal bleeding subscores missing at Week 8 were considered not to be in symptomatic remission. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	72	132	144	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects in with Normal or Inactive Mucosal Disease at Week 8

End point title	Induction Study - Number of Subjects in with Normal or Inactive Mucosal Disease at Week 8

End point description:

Normal or inactive mucosal disease is defined as an endoscopy score of 0. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 or who had a missing endoscopy score at Week 8 were considered not to have normal or inactive mucosal disease. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	12	33	25	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in Mayo score at Week 8

End point title	Induction Study - Change from Baseline in Mayo score at Week 8

End point description:

The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and physician's global assessment), rated as 0 (normal) to 3 (severe). Total score is calculated as the sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5 = mild; 6 to 10 = moderate; and 11 to 12 = severe; higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 had their baseline Mayo score carried forward to Week 8 or who had all 4 Mayo subscores missing at Week 8 had their last available individual Mayo subscores carried forward. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies those subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.8 (± 2.40)	-3.2 (± 2.81)	-3.5 (± 2.67)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in Partial Mayo Score Through Week 8

End point title	Induction Study - Change from Baseline in Partial Mayo Score Through Week 8

End point description:

The partial Mayo score, which is sum of 3 subscores of the Mayo score without the endoscopy subscore (stool frequency, rectal bleeding, and physician's global assessment subscores; rated as 0 [normal] to 3 [severe]). The partial Mayo score is calculated as the sum of the 3 subscores and values range from 0 to 9; higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 had their baseline value carried forward from the time of the event onward. Subjects with the partial Mayo score missing at a timepoint had their last available individual partial Mayo subscore carried forward to that timepoint. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies those subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline through Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	321	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 2	-1.0 (± 1.63)	-1.5 (± 1.74)	-1.6 (± 1.69)	
Change at Week 4	-1.4 (± 1.86)	-2.1 (± 1.86)	-2.5 (± 1.93)	
Change at Week 8	-1.5 (± 2.07)	-2.6 (± 2.31)	-2.9 (± 2.20)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with individual Mayo Subscore (Stool Frequency) up to Week 8

End point title	Induction Study - Number of Subjects with individual Mayo Subscore (Stool Frequency) up to Week 8

End point description:

The stool frequency subscore of Mayo score is rated as 0 (normal) to 3 (severe). Stool frequency scores: 0 =normal number of stools, 1 = 1-2 stools more than normal, 2 = 3-4 stools more than normal, 3 = 5 or more stools more than normal. Higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing Mayo stool frequency subscore at the designated analysis timepoint had the last available value for that subscore carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies those subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Up to Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	321	
Units: Subjects				
Week 2:Normal number of stools	16	32	26	
Week 2:1-2 stools more than normal	82	99	94	
Week 2: 3-4 stools more than normal	85	88	90	
Week 2: 5 or more stools more than normal	136	101	111	
Week 4:Normal number of stools	30	36	50	
Week 4:1-2 stools more than normal	85	122	126	
Week 4: 3-4 stools more than normal	81	78	72	
Week 4: 5 or more stools more than normal	123	84	73	
Week 8:Normal number of stools	28	66	71	
Week 8:1-2 stools more than normal	93	112	110	
Week 8: 3-4 stools more than normal	76	61	85	
Week 8: 5 or more stools more than normal	122	81	55	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with individual Mayo Subscore (Rectal Bleeding) up to Week 8

End point title	Induction Study - Number of Subjects with individual Mayo Subscore (Rectal Bleeding) up to Week 8

End point description:

The rectal bleeding subscore of the Mayo Score is rated as 0 (normal) to 3 (severe). Rectal bleeding scores: 0 = no blood seen, 1 = streaks of blood with stool less than half the time, 2 = obvious blood with stool most of the time, and 3 = blood alone passed. Higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing Mayo rectal bleeding subscore at the designated analysis timepoint had the

last available value for that subscore carried forward. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Up to Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Week 2: No blood seen	83	104	120	
Week 2:Streaks of blood with stool < half time	119	122	131	
Week 2: Obvious blood with stool most of the time	94	83	63	
Week 2: Blood alone passed	23	11	8	
Week 4:No blood seen	117	138	161	
Week 4:Streaks of blood with stool < half time	103	117	115	
Week 4: Obvious blood with stool most of time	75	54	40	
Week 4: Blood alone passed	24	11	6	
Week 8:No blood seen	119	173	204	
Week 8:Streaks of blood with stool < half the time	106	85	81	
Week 8: Obvious blood with stool most of the time	73	54	31	
Week 8: Blood alone passed	21	8	6	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with individual Mayo Subscore (Endoscopy Findings) at Week 8

End point title	Induction Study - Number of Subjects with individual Mayo Subscore (Endoscopy Findings) at Week 8

End point description:

The endoscopy findings subscore of the Mayo score is rated as 0 (normal) to 3 (severe). Endoscopy finding scores: 0 = normal or inactive disease, 1 = mild disease (erythema, decreased vascular pattern, mild friability), 2 = moderate disease (marked erythema, absent vascular pattern, friability, erosions), and 3 = Severe disease (spontaneous bleeding, ulceration). Higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing Mayo endoscopy subscore at Week 8 had the last available value for that subscore carried forward. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Week 8: Normal or inactive disease	12	33	25	
Week 8:Mild disease	32	51	62	
Week 8: Moderate disease	99	96	84	
Week 8: Severe disease	176	140	151	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Individual Mayo Subscore (Physician's Global Assessment) up to Week 8

End point title	Induction Study - Number of Subjects with Individual Mayo Subscore (Physician's Global Assessment) up to Week 8

End point description:

The physician's global assessment subscore of the Mayo score is rated as 0 (normal) to 3 (severe). Physician’s global assessment scores: 0 = normal, 1 = mild disease, 2 = moderate disease, and 3 = severe disease. Higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing Mayo physician’s global assessment subscore at the designated analysis timepoint had the last available value for that subscore carried forward. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Up to Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Week 2: Normal	3	4	10	
Week 2:Mild disease	66	82	81	
Week 2: Moderate disease	194	193	181	
Week 2: Severe disease	56	41	50	

Week 4:Normal	13	14	22	
Week 4:Mild disease	82	118	137	
Week 4: Moderate disease	181	164	138	
Week 4: Severe disease	43	24	25	
Week 8:Normal	21	37	49	
Week 8:Mild disease	83	136	135	
Week 8: Moderate disease	153	115	106	
Week 8: Severe disease	62	32	32	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Clinical Remission at Week 8 by Biologic Failure (BF) Status (As per Global Definition)

End point title	Induction Study - Number of Subjects with Clinical Remission at Week 8 by Biologic Failure (BF) Status (As per Global Definition)

End point description:

Global definition of clinical remission: Mayo score<=2 points, with no individual subscore >1. It included 4 subscores (stool frequency, rectal bleeding, endoscopy findings, PGA), rated as 0 (normal) to 3 (severe). Total score = sum of 4 subscores and range from 0 to 12, where 3 to 5 = mild; 6 to 10 = moderate; 11 to 12 = severe; higher scores indicate worsening of disease. BF: subjects received treatment with 1 or more tumor necrosis factor (TNF) antagonists and/or vedolizumab at dose approved for treatment of UC and did not respond initially or responded initially but lost response or were intolerant of medication. Subjects with prohibited change in concomitant UC medication/ ostomy/colectomy before Week 8 or who had all 4 Mayo subscores missing at Week 8 considered not in clinical remission. PEAS included all subjects randomized in the IS. Here, n (number of subjects analyzed) refer subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Subjects with BF (n= 161, 164, 166)	2	19	21	
Subjects without BF (n= 158, 156, 156)	15	31	29	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Clinical Remission at Week 8 by Biologic Failure (BF) Status (As per US Definition)

End point title	Induction Study - Number of Subjects with Clinical Remission at Week 8 by Biologic Failure (BF) Status (As per US Definition)

End point description:

US definition of clinical remission: absolute stool number <=3, a Mayo rectal bleeding subscore of 0 (no blood seen), Mayo endoscopy subscore of (normal/ inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]), without PGA. Mayo rectal bleeding and endoscopy subscores rated 0 (normal) to 3 (severe). BF: subjects received treatment with 1/ more TNF antagonists/ vedolizumab at dose approved for treatment of UC, and did not respond initially or responded initially but lost response/ intolerant of medication. Subjects with prohibited change in concomitant UC medication/ ostomy/ colectomy before Week 8/ missing all 3 of Mayo components (absolute stool number, rectal bleeding, Mayo endoscopy subscore) at Week 8 considered not in clinical remission. PEAS consisted of all subjects randomized in the induction study. Here, n (number of subjects analyzed) refer subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Subjects with BF (n= 161, 164, 166)	4	19	22	
Subjects without BF (n= 158, 156, 156)	16	34	39	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Endoscopic Healing at Week 8 by Biologic Failure Status

End point title	Induction Study - Number of Subjects with Endoscopic Healing at Week 8 by Biologic Failure Status

End point description:

Number of subjects with endoscopic healing at Week 8 by BF status were reported. Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It is defined as Mayo endoscopic subscore = 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]). BF: Subjects received treatment with 1/ more TNF antagonists and/or vedolizumab at dose approved for treatment of UC, and either did not respond initially, responded initially but then lost response/ were intolerant of medication. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 or who had a missing endoscopy score at Week 8 were considered not to have endoscopic healing. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Subjects with BF (n= 161,164, 166)	11	30	35	
Subjects without BF (n= 158,156, 156)	33	54	52	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Clinical Response at Week 8 by Biologic Failure Status

End point title	Induction Study - Number of Subjects with Clinical Response at Week 8 by Biologic Failure Status

End point description:

Clinical response: decrease from IS baseline in Mayo score by >=30% and >=3 points, with either decrease from baseline in rectal bleeding subscore >=1/rectal bleeding subscore=0/1. Mayo score included 4 subscores (stool frequency, rectal bleeding, endoscopy findings, PGA), rated as 0 (normal) to 3 (severe). Total score=sum of 4 subscores; range: 0 to 12, where 3 to 5=mild; 6 to 10=moderate; 11 to 12=severe; higher scores=worsening of disease. BF: subjects received treatment with 1/more TNF antagonists and/or vedolizumab at dose approved for treatment of UC and did not respond initially or responded initially but lost response/were intolerant of medication. Subjects with prohibited change in concomitant UC medication/ ostomy/ colectomy before Week 8 or who had all 4 Mayo subscores missing at Week 8 were considered not in clinical response. PEAS included all subjects randomized in IS. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects				
Subjects with BF (n= 161,164, 166)	44	74	95	
Subjects without BF (n= 158,156, 156)	56	90	104	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: Number of Subjects in Remission Based on Stool Frequency Subscore of 0 or 1, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 8 (US Specific)

End point title	Induction Study: Number of Subjects in Remission Based on Stool Frequency Subscore of 0 or 1, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 8 (US Specific)

End point description:

Number of subjects in remission based on stool frequency subscore of 0 (normal number of stools) or 1 (1-2 stools more than normal), rectal bleeding subscore of 0 (no blood seen), and endoscopy subscore of 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]) at Week 8 were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who were missing all 3 of the Mayo components related to this OM (stool frequency, rectal bleeding subscore, and Mayo endoscopy subscore) at Week 8 were considered not to be in remission. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	25	60	67	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study: Number of Subjects in Remission Based on Stool Frequency Subscore of 0, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 8 (US Specific)

End point title	Induction Study: Number of Subjects in Remission Based on Stool Frequency Subscore of 0, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 8 (US Specific)

End point description:

Number of subjects in remission based on stool frequency subscore of 0 (normal number of stools), rectal bleeding subscore of 0 (no blood seen), and endoscopy subscore of 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]) at Week 8 were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who were missing all 3 of the Mayo components related to this OM (stool frequency, rectal bleeding subscore, and Mayo endoscopy subscore) at Week 8 were considered not to be in remission. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	10	35	29	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in C-reactive Protein (CRP) Concentration Through Week 8

End point title	Induction Study - Change from Baseline in C-reactive Protein (CRP) Concentration Through Week 8

End point description:

Change from baseline in CRP concentration through Week 8 was reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing CRP value at the designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline through Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	316	315	320	
Units: milligram per liter (mg/L)				
median (inter-quartile range (Q1-Q3))				
Change at Week 2	-0.01 (-2.79 to 1.21)	-0.75 (-4.53 to 0.00)	-0.92 (-6.24 to 0.05)	
Change at Week 4	-0.18 (-3.12 to 0.71)	-1.08 (-5.86 to 0.00)	-1.94 (-7.16 to -0.06)	
Change at Week 8	0.00 (-2.47 to 2.61)	-1.30 (-5.04 to 0.30)	-1.43 (-7.36 to 0.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Normalized CRP (<=3 mg/L) up to Week 8 Among Subjects with Abnormal CRP (>3 mg/L) at Baseline

End point title	Induction Study - Number of Subjects with Normalized CRP (<=3 mg/L) up to Week 8 Among Subjects with Abnormal CRP (>3 mg/L) at Baseline

End point description:

Number of subjects with normalized CRP (<=3 mg/L) up to Week 8 among subjects with abnormal CRP (>3 mg/L) at baseline were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who had a missing CRP value at the designated analysis timepoint were considered not to have normalized CRP. PEAS consisted of all subjects randomized in the induction study, with those subjects who were having abnormal CRP at baseline.

End point type	Secondary

End point timeframe:

Up to Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	185	185	199	
Units: Subjects				
Week 2	36	54	58	
Week 4	41	70	75	
Week 8	39	63	77	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in Fecal Lactoferrin Concentration Through Week 8

End point title	Induction Study - Change from Baseline in Fecal Lactoferrin Concentration Through Week 8

End point description:

Change from baseline in fecal lactoferrin concentration through Week 8 was reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing fecal

lactoferrin value at the designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline through Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	294	302	306	
Units: microgram per gram (mcg/g)				
median (inter-quartile range (Q1-Q3))				
Change at Week 2	0.00 (-103.22 to 120.67)	-4.67 (-140.04 to 75.46)	-24.06 (-202.88 to 60.23)	
Change at Week 4	0.00 (-117.67 to 133.67)	-29.26 (-203.79 to 46.29)	-69.51 (-240.62 to 24.90)	
Change at Week 8	-4.71 (-149.28 to 92.90)	-43.41 (-220.99 to 29.10)	-101.46 (-301.23 to 0.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Normalized Fecal Lactoferrin (<=7.24 mcg/g) up to Week 8 Among Subjects with Abnormal fecal lactoferrin (>7.24 mcg/g) at Baseline

End point title	Induction Study - Number of Subjects with Normalized Fecal Lactoferrin (<=7.24 mcg/g) up to Week 8 Among Subjects with Abnormal fecal lactoferrin (>7.24 mcg/g) at Baseline

End point description:

Number of subjects with normalized fecal lactoferrin (<=7.24 mcg/g) up to Week 8 among subjects with abnormal fecal lactoferrin (> 7.24 mcg/g) at baseline were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who had a missing fecal lactoferrin value at the designated analysis timepoint were considered not to have normalized fecal lactoferrin. PEAS consisted of all subjects randomized in the induction study, with those subjects who had abnormal fecal lactoferrin at baseline.

End point type	Secondary

End point timeframe:

Up to Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	280	291	294	
Units: Subjects				
Week 2	16	17	15	
Week 4	16	37	33	
Week 8	26	50	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in Fecal Calprotectin Concentration Through Week 8

End point title	Induction Study - Change from Baseline in Fecal Calprotectin Concentration Through Week 8

End point description:

Change from baseline in fecal calprotectin concentration through Week 8 was reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from the time of the event onward. Subjects who had a missing fecal calprotectin value at the designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline through Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	289	296	300	
Units: milligram per kilogram (mg/kg)				
median (inter-quartile range (Q1-Q3))				
Change at Week 2	0.00 (-702.00 to 631.00)	-29.00 (-933.50 to 492.00)	-127.00 (-1029.50 to 433.50)	
Change at Week 4	-2.00 (-961.00 to 894.00)	-223.00 (-1200.50 to 266.50)	-485.50 (-1536.50 to 158.50)	
Change at Week 8	-59.00 (-996.00 to 751.00)	-431.50 (-1635.50 to 175.00)	-715.50 (-1913.50 to 0.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with Normalized Fecal Calprotectin (<=250 mg/kg) up to Week 8 Among Subjects with Abnormal Fecal Calprotectin (>250 mg/kg) at Baseline

End point title	Induction Study - Number of Subjects with Normalized Fecal Calprotectin (<=250 mg/kg) up to Week 8 Among Subjects with Abnormal Fecal Calprotectin (>250 mg/kg) at Baseline

End point description:

Number of subjects with normalized fecal calprotectin (<=250 milligram per kilogram [mg/kg) up to Week 8 among subjects with abnormal fecal calprotectin (>250 mg/kg) at baseline were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who had a missing fecal calprotectin value at the designated analysis timepoint were considered not to have normalized fecal calprotectin. PEAS consisted of all randomized subjects in the induction study, with abnormal fecal calprotectin (>250 mg/kg) at baseline.

End point type	Secondary

End point timeframe:

Up to Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	250	264	274	
Units: Subjects				
Week 2	20	37	37	
Week 4	25	45	47	
Week 8	51	64	70	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Number of Subjects with a >20-point Improvement from Baseline in Total Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 8

End point title	Induction Study - Number of Subjects with a >20-point Improvement from Baseline in Total Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 8

End point description:

The IBDQ is 32-item questionnaire for subjects with IBD used to evaluate disease-specific health-related quality of life. IBDQ consists of 32 items, each item score ranged from 1 (worst possible response) to 7 (best possible response). The 32 items were grouped into 4 domains: bowel function, emotional status, systemic symptoms and social function. The 4 domains were scored as follows: 10 to 70 (bowel symptoms); 5 to 35 (systemic symptoms); 12 to 84 (emotional function); and 5 to 35 (social function). For each domain, higher score indicated better quality of life. Total score is sum of each item score and ranges from 32 to 224 with higher score means better quality of life. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy prior to the Week 8 or who had a missing IBDQ score at either baseline or Week 8 were considered not to have achieved a greater than

20-point improvement. PEAS consisted of all subjects randomized in the induction study.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Subjects	118	196	200	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in IBDQ Dimension Scores at Week 8

End point title	Induction Study - Change from Baseline in IBDQ Dimension Scores at Week 8

End point description:

IBDQ questionnaire used to evaluate disease-specific health-related quality of life (QoL), consists of 32 items, each item score ranged from 1 (worst possible response) to 7 (best possible response), which were grouped into 4 domains: bowel function, emotional status, systemic symptoms and social function. These domains were scored as 10 to 70 (bowel symptoms); 5 to 35 (systemic symptoms); 12 to 84 (emotional function);and 5 to 35 (social function). Each domain, higher score means better QoL. Total score is sum of each item score; ranges:32 to 224; higher score means better QoL. Subjects who had prohibited change in concomitant UC medication/ostomy/colectomy prior to Week 8 had their baseline value carried forward from time of event onward and subjects who had missing score at designated analysis timepoint had their last value carried forward. PEAS included all subjects randomized in IS. Here, n (number of subjects analyzed) refers subjects analyzed for this OM at specified category.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	317	319	321	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Bowel: Change at Week 8 (n= 317, 319, 321)	5.9 (± 10.34)	12.5 (± 11.27)	12.7 (± 11.11)	

Emotional: Change at Week 8 (n= 317, 317, 321)	5.3 (± 12.33)	10.1 (± 12.39)	11.2 (± 12.33)	
Systemic: Change at Week 8 (n= 317, 319, 321)	2.3 (± 5.59)	5.1 (± 5.59)	5.2 (± 5.65)	
Social: Change at Week 8 (n= 317, 318, 321)	2.7 (± 6.55)	5.7 (± 7.41)	5.9 (± 6.44)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in 36-Item Short-Form (SF-36) Physical Component Score (PCS) and Mental Component Score (MCS) at Week 8

End point title	Induction Study - Change from Baseline in 36-Item Short-Form (SF-36) Physical Component Score (PCS) and Mental Component Score (MCS) at Week 8

End point description:

SF-36 evaluates 8 individual subscales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health). Each scales scored from 0 to 100 with higher scores= better health. Based on scale scores, physical component summary (PCS: calculated from subscales physical functioning, role-physical, bodily pain, and general health) and mental component summary (MCS: calculated from subscales vitality, social functioning, role-emotional and mental health) scores were derived. Subjects who had prohibited change in concomitant UC medication/ostomy/colectomy prior to Week 8 had their baseline value carried forward from time of event onward or subjects who had missing component summary score at Week 8 had their last value carried forward. PEAS included all subjects randomized in the IS. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	318	322	
Units: Units on a scale				
arithmetic mean (standard deviation)				
PCS: Change at Week 8	2.1 (± 6.39)	4.7 (± 6.49)	5.2 (± 6.16)	
MCS: Change at Week 8	2.2 (± 10.20)	5.3 (± 9.63)	5.1 (± 9.72)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in Individual Subscales of 36-Item Short-Form (SF-36) at Week 8

End point title	Induction Study - Change from Baseline in Individual Subscales of 36-Item Short-Form (SF-36) at Week 8

End point description:

SF-36 evaluates 8 individual subscales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health). Each 8 scales scored from 0 to 100 with higher scores= better health. Subjects who had prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from time of event onward or subjects who had missing individual scale at a designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies subjects who were analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	318	322	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Physical functioning: Change at Week 8	1.7 (± 6.46)	3.0 (± 6.46)	3.4 (± 6.51)	
Role-physical: Change at Week 8	2.4 (± 9.51)	5.9 (± 9.34)	6.1 (± 8.53)	
Bodily pain: Change at Week 8	2.6 (± 9.71)	6.0 (± 9.45)	6.8 (± 9.08)	
General health: Change at Week 8	1.5 (± 7.36)	4.7 (± 7.74)	4.5 (± 7.10)	
Vitality: Change at Week 8	2.7 (± 9.93)	6.1 (± 9.35)	6.8 (± 9.78)	
Social functioning: Change at Week 8	3.0 (± 10.52)	6.6 (± 10.25)	6.4 (± 9.84)	
Role-emotional: Change at Week 8	1.6 (± 11.04)	4.4 (± 11.04)	3.6 (± 10.53)	
Mental health: Change at Week 8	2.0 (± 9.86)	4.7 (± 9.14)	5.1 (± 9.27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in EuroQOL-5 Dimensions (EQ-5D) Health Questionnaire index Score at Week 8

End point title	Induction Study - Change from Baseline in EuroQOL-5 Dimensions (EQ-5D) Health Questionnaire index Score at Week 8

End point description:

EQ-5D descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). The responses to 5 EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 (death) to 1 (full health). Subjects who had prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from time of event onward or subjects who had missing score at a designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies subjects analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	317	319	322	
Units: Units on a scale				
arithmetic mean (standard deviation)	0.04 (± 0.182)	0.09 (± 0.182)	0.11 (± 0.172)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Change from Baseline in EuroQOL-5 Dimensions (EQ-5D) Health State Visual Analog Scale (VAS) Score at Week 8

End point title	Induction Study - Change from Baseline in EuroQOL-5 Dimensions (EQ-5D) Health State Visual Analog Scale (VAS) Score at Week 8

End point description:

The EQ-5D VAS records the subject's self-rated health on a vertical, VAS, with 0 representing the worst imaginable health state and 100 representing the best imaginable health state. The EQ VAS is used as a quantitative measure of health outcome as judged by the individual subjects. Subjects who had prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from time of event onward or subjects who had missing score at a designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects randomized in the induction study. Here, N (number of subjects analyzed) signifies subjects analyzed for this OM.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	317	319	322	
Units: Units on a scale				
arithmetic mean (standard deviation)	5.71 (± 19.584)	13.64 (± 20.394)	13.51 (± 18.447)	

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Study - Percentage of Subjects with Change from Baseline in EuroQOL-5 Dimensions (EQ-5D) Score at Week 8

End point title	Induction Study - Percentage of Subjects with Change from Baseline in EuroQOL-5 Dimensions (EQ-5D) Score at Week 8

End point description:

EQ-5D descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). The responses to 5 EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 (death) to 1 (full health). Subjects who had prohibited change in concomitant UC medication or an ostomy or colectomy prior to Week 8 had their baseline value carried forward from time of event onward or subjects who had missing score at a designated analysis timepoint had their last value carried forward. Percentage of subjects with various responses to the 5 dimensions were reported. PEAS consisted of all subjects randomized in the induction study. Here, n (number of subjects analyzed) signifies subjects who were analyzed for this OM at specified category.

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab approximately 6mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	319	320	322	
Units: Percentage of subjects				
number (not applicable)				
Mobility:Improved at Week 8 (n= 317, 319, 322)	18.0	16.3	24.2	
Mobility:No change at Week 8 (n= 317, 319, 322)	71.9	71.8	66.8	
Mobility:Worsened at Week 8 (n= 317, 319, 322)	10.1	11.9	9.0	
Self-care:Improved at Week 8 (n= 317, 319, 322)	5.4	6.9	7.5	
Self-care:No change at Week 8 (n= 317, 319, 322)	89.6	88.4	90.4	
Self-care:Worsened at Week 8 (n= 317, 319, 322)	5.0	4.7	2.2	
Usual activities:Improved Week 8(n=317,319,322)	34.1	49.5	45.0	
Usual activities:No Change Week 8(n=317,319,322)	51.1	40.4	44.1	
Usual activities:Worsened Week 8(n=317,319,322)	14.8	10.0	10.9	
Pain/discomfort:Improved Week 8(n=319,320,322)	34.4	44.2	43.5	
Pain/discomfort:No Change Week 8(n= 317,319,322)	49.8	48.3	48.1	
Pain/discomfort:Worsened Week 8(n=317,319,322)	15.8	7.5	8.4	

Anxiety/depression:Improved Week 8(n=317,319,322)	26.8	33.5	37.6	
Anxiety/depression:No Change Week 8(n=317,319,322)	55.5	54.2	51.6	
Anxiety/depression:Worsened Week 8(n=317,319,322)	17.7	12.2	10.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Change from Maintenance Baseline in Mayo score at Week 44

End point title	Maintenance Study - Change from Maintenance Baseline in Mayo score at Week 44

End point description:

The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and PGA), rated as 0 (normal) to 3 (severe). Total score is calculated as sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5=mild; 6 to 10=moderate; and 11 to 12=severe; higher scores means worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy , or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to Week 44 had their Week 0 value of the induction study carried forward or who had all 4 Mayo subscores missing at Week 44 had their last available individual Mayo subscores carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Baseline and Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Units on a scale				
arithmetic mean (standard deviation)	1.6 (± 3.45)	0.1 (± 3.02)	-0.5 (± 2.88)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Change from Induction Baseline in Mayo Score at Week 44

End point title	Maintenance Study - Change from Induction Baseline in Mayo Score at Week 44

End point description:

The Mayo score consists of 4 subscores (stool frequency, rectal bleeding, endoscopy findings, and PGA), rated as 0 (normal) to 3 (severe). Total Mayo score is calculated as sum of 4 subscores and values range from 0 to 12 scores, where 3 to 5=mild; 6 to 10=moderate; and 11 to 12=severe; higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication/ostomy/colectomy or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward or who had all 4 Mayo subscores missing at Week 44 had their last available individual Mayo subscores carried forward. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Induction Baseline and Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Units on a scale				
arithmetic mean (standard deviation)	-3.3 (± 3.34)	-5.0 (± 3.27)	-5.6 (± 3.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Number of Subjects with Individual Mayo Subscore (Stool Frequency) up to Week 44

End point title	Maintenance Study - Number of Subjects with Individual Mayo Subscore (Stool Frequency) up to Week 44

End point description:

Stool frequency subscore of Mayo score is rated as 0 (normal) to 3 (severe). Stool frequency scores: 0 =normal number of stools, 1 = 1-2 stools more than normal, 2 = 3-4 stools more than normal, 3 = 5 or more stools more than normal. Higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward or who had a missing Mayo subscores at a timepoint had the last available value for that subscore carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects				
Week 4:Normal number of stools	56	61	58	
Week 4:1-2 stools more than normal	91	76	86	
Week 4: 3-4 stools more than normal	21	26	29	
Week 4: 5 or more stools more than normal	7	9	3	
Week 8:Normal number of stools	70	62	61	
Week 8:1-2 stools more than normal	69	75	84	
Week 8: 3-4 stools more than normal	22	25	26	
Week 8: 5 or more stools more than normal	14	10	5	
Week 12:Normal number of stools	62	55	64	
Week 12:1-2 stools more than normal	72	75	85	
Week 12: 3-4 stools more than normal	20	28	21	
Week 12: 5 or more stools more than normal	21	14	6	
Week 16:Normal number of stools	63	51	73	
Week 16:1-2 stools more than normal	66	78	77	
Week 16: 3-4 stools more than normal	25	27	15	
Week 16: 5 or more stools more than normal	21	16	11	
Week 20:Normal number of stools	59	63	67	
Week 20:1-2 stools more than normal	55	65	85	
Week 20: 3-4 stools more than normal	34	26	15	
Week 20: 5 or more stools more than normal	27	18	9	
Week 24:Normal number of stools	50	64	72	
Week 24:1-2 stools more than normal	63	61	73	
Week 24: 3-4 stools more than normal	31	31	20	
Week 24: 5 or more stools more than normal	31	16	11	
Week 28:Normal number of stools	52	64	67	
Week 28:1-2 stools more than normal	53	64	76	
Week 28: 3-4 stools more than normal	34	24	22	
Week 28: 5 or more stools more than normal	36	20	11	
Week 32:Normal number of stools	51	59	72	
Week 32:1-2 stools more than normal	55	66	73	
Week 32: 3-4 stools more than normal	35	25	18	
Week 32: 5 or more stools more than normal	34	22	13	
Week 36:Normal number of stools	49	59	77	
Week 36:1-2 stools more than normal	52	60	66	
Week 36: 3-4 stools more than normal	36	29	18	
Week 36: 5 or more stools more than normal	38	24	15	
Week 40:Normal number of stools	48	55	81	
Week 40:1-2 stools more than normal	50	65	58	
Week 40: 3-4 stools more than normal	36	26	21	

Week 40: 5 or more stools more than normal	40	26	16	
Week 44:Normal number of stools	46	61	71	
Week 44:1-2 stools more than normal	53	57	72	
Week 44: 3-4 stools more than normal	35	28	16	
Week 44: 5 or more stools more than normal	41	25	17	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Number of Subjects with individual Mayo Subscore (Rectal Bleeding) up to Week 44

End point title	Maintenance Study - Number of Subjects with individual Mayo Subscore (Rectal Bleeding) up to Week 44

End point description:

The rectal bleeding subscore of the Mayo Score is rated as 0 (normal) to 3 (severe). Rectal bleeding scores: 0 = no blood seen, 1 = streaks of blood with stool <half time, 2 = obvious blood with stool most of time, and 3 = blood alone passed. Higher scores = worsening of disease. Subjects who had prohibited change in concomitant UC medication/ ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ due to AE of worsening of UC before Week 44 had their Week 0 value of induction study carried forward from time of event onward and who had missing Mayo subscores at timepoint had last available value for that subscore carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects				
Week 4:No blood seen	149	148	143	
Week 4:Streaks of blood with stool < half time	20	23	29	
Week 4: Obvious blood with stool most of the time	4	1	24	
Week 4: Blood alone passed	2	0	0	
Week 8:No blood seen	139	151	141	
Week 8:Streaks of blood with stool < half time	27	17	31	
Week 8: Obvious blood with stool most of time	6	3	4	
Week 8:Blood alone passed	3	1	0	
Week 12:No blood seen	141	144	149	

Week 12:Streaks of blood with stool <half time	21	19	18	
Week 12: Obvious blood with stool most of the time	10	8	6	
Week 12: Blood alone passed	3	1	3	
Week 16:No blood seen	134	145	150	
Week 16:Streaks of blood with stool < half time	24	17	17	
Week 16: Obvious blood with stool most of the time	13	8	8	
Week 16: Blood alone passed	4	2	1	
Week 20:No blood seen	120	141	144	
Week 20:Streaks of blood with stool <half time	31	17	20	
Week 20: Obvious blood with stool most of the time	19	12	11	
Week 20: Blood alone passed	5	2	1	
Week 24:No blood seen	114	139	144	
Week 24:Streaks of blood with stool <half time	32	18	19	
Week 24: Obvious blood with stool most of the time	23	12	11	
Week 24: Blood alone passed	6	3	2	
Week 28:No blood seen	114	141	147	
Week 28:Streaks of blood with stool <half time	26	18	12	
Week 28: Obvious blood with stool most of the time	28	10	14	
Week 28: Blood alone passed	7	3	3	
Week 32:No blood seen	109	138	147	
Week 32:Streaks of blood with stool <half time	32	16	13	
Week 32: Obvious blood with stool most of the time	25	14	14	
Week 32: Blood alone passed	9	4	2	
Week 36:No blood seen	108	136	150	
Week 36:Streaks of blood with stool <half time	30	18	9	
Week 36: Obvious blood with stool most of the time	28	15	15	
Week 36: Blood alone passed	9	3	2	
Week 40:No blood seen	105	132	147	
Week 40:Streaks of blood with stool <half time	33	22	10	
Week 40: Obvious blood with stool most of the time	28	13	17	
Week 40: Blood alone passed	9	5	2	
Week 44:No blood seen	101	137	139	
Week 44::Streaks of blood with stool <half time	35	15	16	
Week 44: Obvious blood with stool most of the time	30	15	19	
Week 44: Blood alone passed	9	5	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Number of Subjects with individual Mayo Subscore (Endoscopy Findings) at Week 44

End point title	Maintenance Study - Number of Subjects with individual Mayo Subscore (Endoscopy Findings) at Week 44

End point description:

The endoscopy findings subscore of the Mayo score is rated as 0 (normal) to 3 (severe). Endoscopy finding scores: 0=normal/ inactive disease, 1=mild disease (erythema, decreased vascular pattern, mild friability), 2 =moderate disease (marked erythema, absent vascular pattern, friability, erosions), and 3 =severe disease (spontaneous bleeding, ulceration). Higher scores=worse disease. Subjects who had prohibited change in concomitant UC medication/ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 had Week 0 value of induction study carried forward from time of event onward and who had missing endoscopy subscores at timepoint had last available value for that subscore carried forward. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects				
Week 44: Normal or inactive disease	33	43	52	
Week 44:Mild disease	21	37	42	
Week 44: Moderate disease	40	42	50	
Week 44: Severe disease	81	50	32	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Number of Subjects with individual Mayo Subscore (Physician's Global Assessment) up to Week 44

End point title	Maintenance Study - Number of Subjects with individual Mayo Subscore (Physician's Global Assessment) up to Week 44

End point description:

The physician's global assessment subscore of the Mayo score is rated as 0 (normal) to 3 (severe). Physician’s global assessment scores: 0 = normal, 1 = mild disease, 2 = moderate disease, and 3 = severe disease. Higher scores indicate worsening of the disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward and who had a missing Mayo subscores at a timepoint had the last available value for that subscore carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w,

ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects				
Week 4:Normal	62	61	59	
Week 4:Mild disease	100	99	105	
Week 4: Moderate disease	12	12	11	
Week 4: Severe disease	1	0	1	
Week 8:Normal	65	70	76	
Week 8:Mild disease	90	89	88	
Week 8: Moderate disease	17	13	11	
Week 8:Severe disease	3	0	1	
Week 12:Normal	66	68	73	
Week 12:Mild disease	79	81	88	
Week 12: Moderate disease	26	16	14	
Week 12: Severe disease	4	7	1	
Week 16:Normal	67	82	83	
Week 16:Mild disease	68	69	78	
Week 16: Moderate disease	32	14	13	
Week 16: Severe disease	8	7	2	
Week 20:Normal	64	85	84	
Week 20:Mild disease	57	63	73	
Week 20: Moderate disease	41	16	16	
Week 20: Severe disease	12	8	3	
Week 24:Normal	54	84	91	
Week 24:Mild disease	61	65	68	
Week 24: Moderate disease	44	14	15	
Week 24: Severe disease	16	9	2	
Week 28:Normal	58	86	89	
Week 28:Mild disease	52	63	65	
Week 28: Moderate disease	47	14	20	
Week 28: Severe disease	18	9	2	
Week 32:Normal	55	84	92	
Week 32:Mild disease	52	56	62	
Week 32: Moderate disease	46	23	19	
Week 32: Severe disease	22	9	3	
Week 36: Normal	59	78	93	
Week 36:Mild disease	45	60	60	
Week 36: Moderate disease	47	24	19	
Week 36: Severe disease	24	10	4	
Week 40:Normal	57	83	91	

Week 40:Mild disease	48	50	60	
Week 40: Moderate disease	44	24	21	
Week 40: Severe disease	26	15	4	
Week 44:Normal	47	78	85	
Week 44:Mild disease	44	54	62	
Week 44:Moderate disease	57	24	25	
Week 44: Severe disease	27	16	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Change from Maintenance Baseline in Partial Mayo Score Through Week 44

End point title	Maintenance Study - Change from Maintenance Baseline in Partial Mayo Score Through Week 44

End point description:

The partial Mayo score, which is sum of 3 subscores of the Mayo score without the endoscopy subscore (stool frequency, rectal bleeding, and PGA subscores), rated as 0 (normal) to 3 (severe). Total score is sum of 3 subscores and values range from 0 to 9; higher scores means worse disease. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the IS carried forward from the time of the event onward. Subjects who had a missing partial Mayo score at a time point had their last available individual partial Mayo subscore carried forward to that time point. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Baseline through Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4	-0.2 (± 1.24)	-0.3 (± 1.23)	-0.1 (± 1.26)	
Change at Week 8	-0.1 (± 1.59)	-0.3 (± 1.15)	-0.2 (± 1.44)	
Change at Week 12	0.1 (± 1.82)	0.0 (± 1.66)	-0.2 (± 1.63)	
Change at Week 16	0.3 (± 2.07)	-0.1 (± 1.76)	-0.3 (± 1.76)	
Change at Week 20	0.6 (± 2.36)	-0.1 (± 1.91)	-0.2 (± 1.92)	
Change at Week 24	0.9 (± 2.34)	0.0 (± 2.02)	-0.3 (± 1.88)	
Change at Week 28	1.0 (± 2.53)	-0.1 (± 1.95)	-0.2 (± 1.94)	
Change at Week 32	1.1 (± 2.60)	0.1 (± 2.12)	-0.2 (± 1.96)	
Change at Week 36	1.2 (± 2.62)	0.2 (± 2.13)	-0.2 (± 2.08)	
Change at Week 40	1.3 (± 2.64)	0.3 (± 2.27)	-0.2 (± 1.97)	

Change at Week 44	1.5 (± 2.63)	0.3 (± 2.29)	0.0 (± 2.09)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study - Change from Induction Baseline in Partial Mayo Score Through Week 44

End point title	Maintenance Study - Change from Induction Baseline in Partial Mayo Score Through Week 44

End point description:

The partial Mayo score, which is sum of 3 subscores of the Mayo score without the endoscopy subscore (stool frequency, rectal bleeding, and PGA subscores; rated as 0 [normal] to 3 [severe]). Total score is sum of the 3 subscores and values range from 0 to 9; higher scores means worse disease. Subjects who had a prohibited change in concomitant UC medication/ostomy/colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the IS carried forward from the time of the event onward. Subjects who had a missing partial Mayo score at a time point had their last available individual partial Mayo subscore carried forward to that time point. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Baseline through Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4	-4.2 (± 1.70)	-4.5 (± 1.76)	-4.4 (± 1.72)	
Change at Week 8	-4.1 (± 1.80)	-4.5 (± 1.68)	-4.5 (± 1.85)	
Change at Week 12	-3.9 (± 2.07)	-4.2 (± 2.02)	-4.5 (± 2.02)	
Change at Week 16	-3.7 (± 2.17)	-4.3 (± 2.07)	-4.6 (± 2.08)	
Change at Week 20	-3.4 (± 2.26)	-4.3 (± 2.13)	-4.5 (± 2.13)	
Change at Week 24	-3.1 (± 2.36)	-4.2 (± 2.26)	-4.5 (± 2.18)	
Change at Week 28	-3.0 (± 2.49)	-4.3 (± 2.26)	-4.4 (± 2.27)	
Change at Week 32	-2.9 (± 2.51)	-4.1 (± 2.40)	-4.5 (± 2.30)	
Change at Week 36	-2.8 (± 2.43)	-4.0 (± 2.43)	-4.5 (± 2.40)	
Change at Week 40	-2.7 (± 2.51)	-3.9 (± 2.46)	-4.5 (± 2.39)	
Change at Week 44	-2.5 (± 2.52)	-3.9 (± 2.49)	-4.3 (± 2.48)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of subjects in Remission Based on Stool Frequency Subscore of 0 or 1, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 44

End point title	Maintenance Study: Number of subjects in Remission Based on Stool Frequency Subscore of 0 or 1, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 44

End point description:

Number of subjects in remission based on stool frequency subscore of 0 (normal number of stools) or 1 (1-2 stools more than normal), rectal bleeding subscore of 0 (no blood seen), and endoscopy subscore of 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]) at Week 44 were reported. Subjects who had a prohibited change in concomitant UC medication/ostomy/colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 and who were missing all 3 of the Mayo subscores related to this OM (stool frequency, rectal bleeding subscore, and Mayo endoscopy subscore) at Week 44 were considered not to be in remission. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects	49	70	84	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects in Remission Based on Stool Frequency Subscore of 0, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 44

End point title	Maintenance Study: Number of Subjects in Remission Based on Stool Frequency Subscore of 0, Rectal Bleeding Subscore of 0, and Endoscopy Subscore of 0 or 1 at Week 44

End point description:

Number of subjects in remission based on stool frequency subscore of 0 (normal number of stools), rectal bleeding subscore of 0 (no blood seen), and endoscopy subscore of 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]) at Week 44 were reported. Subjects who had a prohibited change in concomitant UC medication/ostomy/colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 or who were missing all 3 of the Mayo subscores related to this OM (stool frequency, rectal bleeding subscore, and Mayo endoscopy subscore) at Week 44 were considered not to be in remission. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab

90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	30	42	48	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission at Week 44 by Biologic Failure Status (As per Global Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission at Week 44 by Biologic Failure Status (As per Global Definition)

End point description:

Global definition of clinical remission: Mayo score <=2 points, with no individual subscore >1. Mayo score included 4 subscores (stool frequency, rectal bleeding, endoscopy findings, physician's global assessment), rated as 0 (normal) to 3 (severe). Total score =sum of 4 subscores and range from 0 to 12, where 3 to 5=mild; 6 to 10=moderate; 11 to 12=severe; higher scores=worsening of disease. BF: participants received treatment with 1/ more TNF antagonists/ vedolizumab at dose approved for treatment of UC, and did not respond initially or responded initially but lost response/ were intolerant of medication. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) refers subjects who were analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects				
Participants with BF (n=88, 70, 91)	15	16	36	
Participants without BF (n= 87, 102, 85)	27	50	41	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects in Symptomatic Remission at Week 44

End point title	Maintenance Study: Number of Subjects in Symptomatic Remission at Week 44

End point description:

Symptomatic remission was defined as a Mayo stool frequency subscore of 0 (normal number of stools) or 1 (1-2 stools more than normal) and a rectal bleeding subscore of 0 (no blood seen). Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 were considered not to be in symptomatic remission from the time of the event onward. Subjects who had both stool frequency and rectal bleeding subscores missing at Week 44 were considered not to be in symptomatic remission for that visit. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects	79	107	119	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission at Week 44 by Biologic Failure Status (As per US Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission at Week 44 by Biologic Failure Status (As per US Definition)

End point description:

US definition of clinical remission: absolute stool number <=3, Mayo rectal bleeding subscore: 0 (no blood seen), Mayo endoscopy subscore: 0(normal/ inactive disease) or 1(mild disease [erythema, decreased vascular pattern, mild friability]). Absolute stool number: average of daily stool number over 3 days. Mayo rectal bleeding and endoscopy subscores: 0(normal) to 3(severe). BF: subjects received

1/ more TNF antagonists/ vedolizumab for treatment of UC, not responded initially/ responded initially but lost response/ were intolerant of medicines. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects				
Subjects with BF (n=88, 70, 91)	15	17	34	
Subjects without BF (n=87, 102, 85)	28	51	41	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Response up to Week 44 by Biologic Failure Status

End point title	Maintenance Study: Number of Subjects with Clinical Response up to Week 44 by Biologic Failure Status

End point description:

Clinical response: decrease from IS baseline in Mayo score by >=30% and >=3 points, with either decrease from baseline in RB subscore >=1/ RB subscore of 0/ 1. Mayo score have 4 subscores (SF, RB, endoscopy findings, PGA), rated 0(normal) to 3(severe). Total score=sum of 4 subscores and range from 0 to 12, where 3 to 5=mild; 6 to 10=moderate; 11 to 12=severe; higher scores=worsening of disease. BF: subjects received treatment: 1/ more TNF antagonists/ vedolizumab for treating UC, no respond initially/responded initially but lost response/ medication intolerant. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects				

Subjects with BF (n= 88, 70, 91)	34	39	59	
Subjects without BF (87, 102, 85)	44	78	66	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Endoscopic Healing at Week 44 by Biologic Failure Status

End point title	Maintenance Study: Number of Subjects with Endoscopic Healing at Week 44 by Biologic Failure Status

End point description:

Number of subjects with endoscopic healing at week 44 by BF status were reported. Endoscopic healing is improvement in endoscopic appearance of mucosa. It is defined as Mayo endoscopic subscore = 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]). BF: subjects received treatment with 1 or more tumor necrosis factor (TNF) antagonists or vedolizumab at dose approved for treatment of UC, and either did not respond initially, responded initially but then lost response, or were intolerant of medication. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM with specified category.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: subjects				
Subjects with BF (n=88, 70, 91)	20	18	41	
Subjects without BF (n= 87, 102, 85)	30	57	49	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Endoscopic Healing at Week 44 Among Subjects who had Achieved Endoscopic Healing at Maintenance Baseline

End point title	Maintenance Study: Number of Subjects with Endoscopic Healing at Week 44 Among Subjects who had Achieved Endoscopic Healing at Maintenance Baseline

End point description:

Endoscopic healing is improvement in the endoscopic appearance of the mucosa. It is defined as Mayo endoscopic subscore = 0 (normal or inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]). Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 or who had a missing endoscopy score at Week 44 were considered not to have endoscopic healing. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects who had achieved endoscopic healing at maintenance baseline.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	68	57	
Units: subjects	25	41	37	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Normal or Inactive Mucosal Disease at Week 44

End point title	Maintenance Study: Number of Subjects with Normal or Inactive Mucosal Disease at Week 44

End point description:

Normal or inactive mucosal disease is defined as an endoscopy score of 0. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 or who had a missing endoscopy score at Week 44 were considered not to have endoscopic healing. Endoscopy subscore as assessed during central review of video of endoscopy was used. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Subjects	32	41	51	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission at Week 44 and not Receiving Concomitant Corticosteroids at Week 44 Among Subjects who Received Concomitant Corticosteroids at Maintenance Baseline (per US Definition)

End point title	Maintenance Study: Number of Subjects with Clinical Remission at Week 44 and not Receiving Concomitant Corticosteroids at Week 44 Among Subjects who Received Concomitant Corticosteroids at Maintenance Baseline (per US Definition)

End point description:

US definition of clinical remission: absolute stool number <=3, a Mayo rectal bleeding subscore of 0 (no blood seen), and Mayo endoscopy subscore of 0(normal/ inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]), without PGA. Absolute stool number is average of daily stool number over 3 days. Mayo rectal bleeding and endoscopy findings subscores rated as 0 (normal) to 3 (severe). Subjects with missing value in corticosteroid use had last value carried forward. Endoscopy subscore assessed during central review of video of endoscopy was used. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects who were receiving concomitant corticosteroids at maintenance baseline.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	82	92	
Units: subjects	18	27	34	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Clinical Remission at Week 44 and not Receiving Concomitant Corticosteroids at Week 44 Among Subjects who Received Concomitant Corticosteroids at Maintenance Baseline (per Global

Definition)	
End point title	Maintenance Study: Number of Subjects with Clinical Remission at Week 44 and not Receiving Concomitant Corticosteroids at Week 44 Among Subjects who Received Concomitant Corticosteroids at Maintenance Baseline (per Global Definition)

End point description:

Global definition of clinical remission: Mayo score <=2 points, with no individual subscore >1. Mayo score includes 4 subscores (stool frequency, rectal bleeding, endoscopy findings, physician's global assessment), rated 0(normal) to 3(severe). Total score=sum of 4 subscores, range: 0 to 12, where 3 to 5=mild; 6 to 10=moderate; 11 to 12=severe; higher scores=worsening of disease. Subjects with all 4 Mayo subscores missing at Week 44 considered not in clinical remission. subjects missing value in corticosteroid use had their last value carried forward. PEAS consisted of all Subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC with, subjects who were receiving concomitant corticosteroids at maintenance baseline.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	82	92	
Units: Subjects	17	25	36	

Statistical analyses

No statistical analyses for this end point

Secondary: MS: Change from Maintenance Baseline in Average Daily P.Eq Corticosteroid Dose Through Week 44 Among Subjects who Received Corticosteroids Other Than Budesonide and Beclomethasone Dipropionate at Maintenance Baseline

End point title	MS: Change from Maintenance Baseline in Average Daily P.Eq Corticosteroid Dose Through Week 44 Among Subjects who Received Corticosteroids Other Than Budesonide and Beclomethasone Dipropionate at Maintenance Baseline

End point description:

The change from maintenance baseline in average daily prednisone-equivalent (P.Eq) corticosteroid dose through Week 44 among the subjects receiving concomitant corticosteroids other than budesonide and beclomethasone dipropionate at maintenance baseline was reported. Subjects who had prohibited change in UC medication/ ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward. Subjects who had a missing value in corticosteroid use at a timepoint had their last available value carried forward to that timepoint. PEAS consisted of all subjects who were in clinical response to IV ustekinumab IS and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects who were receiving concomitant corticosteroids at maintenance baseline.

End point type	Secondary

End point timeframe:

Baseline Through Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	69	82	
Units: milligram per day (mg/day)				
arithmetic mean (standard deviation)				
Change at Week 4	-7.4 (± 5.73)	-7.8 (± 5.48)	-7.2 (± 5.42)	
Change at Week 8	-10.8 (± 6.77)	-11.7 (± 8.17)	-12.1 (± 6.81)	
Change at Week 12	-10.1 (± 8.7)	-11.6 (± 9.16)	-12.6 (± 7.00)	
Change at Week 16	-10.1 (± 7.73)	-12.1 (± 8.37)	-12.8 (± 6.98)	
Change at Week 20	-9.5 (± 7.85)	-12.0 (± 8.44)	-12.6 (± 7.27)	
Change at Week 24	-8.9 (± 7.96)	-11.9 (± 8.62)	-12.5 (± 7.88)	
Change at Week 28	-7.8 (± 8.72)	-11.5 (± 9.23)	-12.4 (± 7.56)	
Change at Week 32	-7.7 (± 8.18)	-11.4 (± 8.98)	-12.1 (± 8.21)	
Change at Week 36	-7.6 (± 8.28)	-11.3 (± 8.80)	-11.7 (± 8.34)	
Change at Week 40	-7.2 (± 8.04)	-11.5 (± 8.62)	-11.5 (± 8.37)	
Change at Week 44	-6.8 (± 7.98)	-11.0 (± 8.87)	-11.5 (± 8.37)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects not Receiving Concomitant Corticosteroids at Week 44 Among Subjects who Received Concomitant Corticosteroids at Maintenance Baseline

End point title	Maintenance Study: Number of Subjects not Receiving Concomitant Corticosteroids at Week 44 Among Subjects who Received Concomitant Corticosteroids at Maintenance Baseline

End point description:

Number of subjects not receiving concomitant corticosteroids at Week 44 among subjects who received concomitant corticosteroids at maintenance Baseline were reported. Subjects who had prohibited change in UC medication/ ostomy/ colectomy/ used rescue medication after clinical flare/ discontinued study agent due to lack of therapeutic effect/ AE of worsening of UC before Week 44 considered to be receiving concomitant corticosteroids at Week 44. Subjects who had a missing value in corticosteroid use at Week 44 had their last value carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC with, subjects who were receiving concomitant corticosteroids at maintenance baseline.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	82	92	
Units: Subjects	43	56	73	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects who Maintained 20-point Improvement from Induction Baseline in IBDQ up to Week 44 Among Subjects with a >20-point Improvement in IBDQ at Maintenance Baseline

End point title	Maintenance Study: Number of Subjects who Maintained 20-point Improvement from Induction Baseline in IBDQ up to Week 44 Among Subjects with a >20-point Improvement in IBDQ at Maintenance Baseline

End point description:

IBDQ consists of 32 items questionnaire, each item score ranged from 1 (worst possible response) to 7 (best possible response). The 32 items were grouped into 4 domains: bowel function, emotional status, systemic symptoms and social function. The 4 domains were scored as:10 to 70 (bowel symptoms); 5 to 35 (systemic symptoms); 12 to 84 (emotional function); and 5 to 35 (social function). For each domain, higher score indicated better quality of life. Total score is sum of each item score and ranges from 32 to 224 with higher score indicating better quality of life UC. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects with >20-point Improvement in IBDQ at the maintenance baseline.

End point type	Secondary

End point timeframe:

Up to Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	129	144	143	
Units: subjects	64	95	102	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in the IBDQ Score at Week 20 and 44

End point title	Maintenance Study: Change from Maintenance Baseline in the

	IBDQ Score at Week 20 and 44

End point description:

IBDQ consists of 32 items questionnaire , each item score ranged from 1 (worst possible response) to 7 (best possible response). The 32 items were grouped into 4 domains: bowel function, emotional status, systemic symptoms and social function. The 4 domains were scored as follows: 10 to 70 (bowel symptoms); 5 to 35 (systemic symptoms); 12 to 84 (emotional function); and 5 to 35 (social function). For each domain, higher score indicated better quality of life. Total score is sum of each item score and ranges from 32 to 224 with higher score indicating better quality of life. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the MS to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Week 20, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	173	172	174	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 20 (n= 174, 172, 174)	-7.0 (± 31.37)	0.8 (± 29.05)	5.5 (± 27.40)	
Change at Week 44 (n= 173, 172, 174)	-15.1 (± 35.43)	-3.0 (± 32.89)	3.9 (± 31.54)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in the IBDQ Dimension Scores at Week 20 and 44

End point title	Maintenance Study: Change from Maintenance Baseline in the IBDQ Dimension Scores at Week 20 and 44

End point description:

IBDQ consists of 32 items questionnaire , each item score ranged from 1 (worst possible response) to 7 (best possible response). The 32 items were grouped into 4 domains: bowel function, emotional status, systemic symptoms and social function. The 4 domains were scored as: 10 to 70 (bowel symptoms); 5 to 35 (systemic symptoms); 12 to 84 (emotional function); 5 to 35 (social function). For each domain, higher score indicated better quality of life. Total score is sum of each item score and ranges from 32 to 224 with higher score indicating better quality of life. PEAS included all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM for specified categories at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Week 20, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	174	172	174	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Bowel:Change at Week 20 (n= 174, 172, 174)	-3.2 (± 10.88)	-0.5 (± 9.16)	1.3 (± 9.56)	
Bowel:Change at Week 44 (n= 173, 172, 174)	-5.7 (± 12.34)	-1.6 (± 10.99)	0.8 (± 10.49)	
Emotional: Change at Week 20 (n= 174, 172, 174)	-1.9 (± 12.16)	0.9 (± 11.12)	2.2 (± 10.56)	
Emotional: Change at Week 44 (n= 173, 172, 174)	-4.7 (± 13.84)	-0.5 (± 12.17)	1.4 (± 12.22)	
Systemic: Change at Week 20 (n= 174, 172, 174)	-1.1 (± 5.54)	0.0 (± 5.31)	0.7 (± 5.24)	
Systemic: Change at Week 44 (n= 173, 172, 174)	-2.2 (± 5.52)	-0.5 (± 5.97)	0.5 (± 5.83)	
Social: Change at Week 20 (n= 174, 172, 174)	-0.7 (± 5.93)	0.3 (± 6.59)	1.4 (± 5.44)	
Social: Change at Week 44 (n= 173, 172, 174)	-2.5 (± 6.72)	-0.5 (± 7.10)	1.1 (± 6.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in 36-Item Short-Form (SF-36) Physical Component Score (PCS) and Mental Component Score (MCS) at Weeks 20 and 44

End point title	Maintenance Study: Change from Maintenance Baseline in 36-Item Short-Form (SF-36) Physical Component Score (PCS) and Mental Component Score (MCS) at Weeks 20 and 44

End point description:

SF-36 evaluates 8 individual subscales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, mental health). Each 8 scales scored from 0 to 100 with higher scores= better health. Based on scale scores, PCS (calculated from subscales physical functioning, role-physical, bodily pain, and general health) and MCS (calculated from subscales vitality, social functioning, role-emotional and mental health) scores were derived. Summary MCS and PCS score is also scaled from 0 to 100 with higher scores= better health. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 20, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	173	172	175	
Units: Units on a scale				
arithmetic mean (standard deviation)				
PCS: Change at Week 20	-1.2 (± 6.20)	-0.2 (± 6.15)	0.8 (± 5.55)	
PCS: Change at Week 44	-1.7 (± 6.45)	-0.4 (± 7.14)	1.3 (± 5.68)	
MCS: Change at Week 20	-1.1 (± 8.90)	1.0 (± 8.91)	0.4 (± 9.10)	
MCS: Change at Week 44	-2.4 (± 9.89)	0.3 (± 8.41)	0.3 (± 9.51)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in Individual Subscales of 36-Item Short-Form (SF-36) at Weeks 20 and 44

End point title	Maintenance Study: Change from Maintenance Baseline in Individual Subscales of 36-Item Short-Form (SF-36) at Weeks 20 and 44

End point description:

SF-36 evaluates 8 individual subscales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health). Each 8 scales scored from 0 to 100 with higher scores= better health. Subjects who had prohibited change in concomitant UC medication/ ostomy/ colectomy/ used rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to AE of worsening of UC prior to Week 44 had Week 0 value of induction study carried forward from time of event onward and subjects with missing individual scale score at timepoint had last available value carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 20, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Physical functioning: Change at Week 20	-0.61 (± 6.140)	-0.01 (± 5.506)	0.51 (± 4.809)	
Physical functioning: Change at Week 44	-1.40 (± 5.932)	-0.44 (± 5.624)	0.66 (± 4.819)	
Role-physical: Change at Week 20	-0.61 (± 8.630)	0.17 (± 7.996)	0.23 (± 8.144)	

Role-physical: Change at Week 44	-2.27 (± 9.400)	-0.84 (± 8.293)	1.08 (± 8.096)	
Bodily pain:Change at Week 20	-2.80 (± 9.081)	-0.30 (± 8.556)	1.06 (± 8.971)	
Bodily pain:Change at Week 44	-2.33 (± 9.245)	0.23 (± 9.340)	0.94 (± 8.350)	
General health:Change at Week 20	-0.95 (± 7.468)	0.67 (± 7.802)	1.14 (± 7.133)	
General health:Change at Week 44	-1.62 (± 7.449)	0.24 (± 8.722)	1.92 (± 7.955)	
Vitality:Change at Week 20	-1.71 (± 8.876)	0.74 (± 8.917)	0.39 (± 9.209)	
Vitality:Change at Week 44	-3.18 (± 10.389)	0.11 (± 9.152)	0.53 (± 9.743)	
Social functioning: Change at Week 20	-0.87 (± 9.245)	0.47 (± 8.979)	0.72 (± 9.907)	
Social functioning: Change at Week 44	-1.83 (± 10.186)	0.06 (± 9.515)	1.12 (± 9.678)	
Role-emotional: Change at Week 20	-0.93 (± 9.586)	0.47 (± 9.338)	0.14 (± 8.637)	
Role-emotional: Change at Week 44	-2.21 (± 10.187)	0.04 (± 9.324)	0.10 (± 8.199)	
Mental health:Change at Week 20	-1.07 (± 9.085)	1.08 (± 8.631)	0.61 (± 8.467)	
Mental health:Change at Week 44	-2.15 (± 9.992)	0.06 (± 8.042)	0.53 (± 8.915)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in EuroQOL-5 Dimensions (EQ-5D) Health Questionnaire index Score at Weeks 20 and 44

End point title	Maintenance Study: Change from Maintenance Baseline in EuroQOL-5 Dimensions (EQ-5D) Health Questionnaire index Score at Weeks 20 and 44

End point description:

EQ-5D descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). The responses to 5 EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 (death) to 1 (full health). PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 20, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	173	172	175	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 20	-0.036 (± 0.1535)	-0.002 (± 0.1694)	0.016 (± 0.1471)	
Change at Week 44	-0.048 (± 0.1587)	0.008 (± 0.1656)	0.025 (± 0.1674)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in EuroQOL-5 (EQ-5D) Health State Visual Analog Scale (VAS) Score at Weeks 20 and 44

End point title	Maintenance Study: Change from Maintenance Baseline in EuroQOL-5 (EQ-5D) Health State Visual Analog Scale (VAS) Score at Weeks 20 and 44

End point description:

The EQ-5D VAS records the participant's self-rated health on a vertical, VAS, with 0 representing the worst imaginable health state and 100 representing the best imaginable health state. The EQ VAS is used as a quantitative measure of health outcome as judged by the individual subjects. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 20 and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	173	172	175	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 20	-4.0 (± 16.70)	-0.3 (± 17.29)	2.6 (± 17.80)	
Change at Week 44	-7.7 (± 18.75)	-2.2 (± 19.87)	2.4 (± 17.28)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Percentage of Subjects with Change from Maintenance Baseline in EuroQOL-5 (EQ-5D) Dimensions Score at Weeks 20 and 44

End point title	Maintenance Study: Percentage of Subjects with Change from Maintenance Baseline in EuroQOL-5 (EQ-5D) Dimensions Score at Weeks 20 and 44

End point description:

EQ-5D descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). The responses to 5 EQ-5D dimensions were scored using a utility-weighted algorithm to derive an EQ-5D health status index score between 0 (death) to 1 (full health). Percentage of subjects with various responses to the 5 dimensions were reported. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects who were analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 20, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	172	176	
Units: Percentage of Subjects				
number (not applicable)				
Change at Week (W) 20: Mobility:Improved	12.7	10.5	13.7	
Change at W 20:Mobility:No change	75.7	79.1	78.9	
Change at W 20:Mobility:Worsened	11.6	10.5	7.4	
Change at W 44:Mobility:Improved	9.8	11.6	12.0	
Change at W 44:Mobility:No change	75.1	76.2	79.4	
Change at W 44:Mobility:Worsened	15.0	12.2	8.6	
Change at W 20:Self-care:Improved	1.7	1.7	4.0	
Change at W 20:Self-care:No change	91.9	93.6	93.7	
Change at W 20:Self-care:Worsened	6.4	4.7	2.3	
Change at W 44:Self-care:Improved	1.7	2.3	4.0	
Change at W 44:Self-care:No change	95.4	93.0	93.1	
Change at W 44:Self-care:Worsened	2.9	4.7	2.9	
Change at W 20:Usual activities:Improved	12.7	17.4	22.3	
Change at W 20:Usual activities:No Change	64.2	66.9	64.0	
Change at W 20:Usual activities:Worsened	23.1	15.7	13.7	
Change at W 44: Usual activities:Improved	14.5	24.4	25.1	
Change at W 44:Usual activities:No Change	52.6	55.2	62.9	
Change at W 44:Usual activities:Worsened	32.9	20.3	12.0	

Change at W 20:Pain/discomfort: Improved	16.8	22.1	23.4	
Change at W 20:Pain/discomfort: No Change	54.9	58.7	58.9	
Change at W 20:Pain/discomfort: Worsened	28.3	19.2	17.7	
Change at W 44:Pain/discomfort: Improved	17.9	25.0	30.3	
Change at W 44:Pain/discomfort: No Change	46.2	55.8	50.9	
Change at W 44:Pain/discomfort: Worsened	35.8	19.2	18.9	
Change at W 20:Anxiety/depression: Improved	16.2	20.3	24.6	
Change at W 20:Anxiety/depression: No Change	62.4	61.6	58.3	
Change at W 20:Anxiety/depression: Worsened	21.4	18.0	17.1	
Change at W 44:Anxiety/depression: Improved	17.9	20.3	26.9	
Change at W 44:Anxiety/depression: No Change	56.1	58.7	58.9	
Change at W 44:Anxiety/depression: Worsened	26.0	20.9	14.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in C-reactive Protein (CRP) Concentration at Weeks 8, 24, and 44

End point title	Maintenance Study: Change from Maintenance Baseline in C-reactive Protein (CRP) Concentration at Weeks 8, 24, and 44

End point description:

Change from Maintenance baseline in CRP concentration at Weeks 8, 24, and 44 were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward. Subjects who had a missing CRP value at the designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects who were analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 24, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	174	170	176	
Units: milligram per liter (mg/L)				
median (inter-quartile range (Q1-Q3))				
Change at Week 8 (n= 174, 172, 176)	0.05 (-0.67 to 0.81)	-0.03 (-0.92 to 0.37)	-0.04 (-1.50 to 0.92)	
Change at Week 24 (n= 174, 172, 176)	0.68 (-0.28 to 2.34)	0.13 (-0.75 to 1.16)	-0.03 (-1.53 to 0.59)	
Change at Week 44 (n= 174, 172, 175)	1.07 (0.00 to 5.18)	0.38 (-0.35 to 1.53)	-0.07 (-1.73 to 0.79)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Number of Subjects with Mucosal Healing at Week 44

End point title	Maintenance Study: Number of Subjects with Mucosal Healing at Week 44

End point description:

Mucosal healing included EH and HH. EH: endoscopy subscore of 0 (normal/ inactive disease) or 1 (mild disease [erythema, decreased vascular pattern, mild friability]). HH: neutrophil infiltration in <5% of crypts, no crypt destruction, no erosions/ ulcerations/ granulation tissue. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC, with subjects whose mucosal healing status was determined at Week 44 with evaluable biopsy.

End point type	Secondary

End point timeframe:

Week 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	172	
Units: Subjects	41	66	79	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in Fecal

Lactoferrin Concentration at Weeks 8, 24, and 44

End point title	Maintenance Study: Change from Maintenance Baseline in Fecal Lactoferrin Concentration at Weeks 8, 24, and 44

End point description:

Change from Maintenance baseline in fecal lactoferrin concentration at Weeks 8, 24, and 44 were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward. Subjects who had a missing fecal lactoferrin value at the designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects who were analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 24, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	161	163	
Units: microgram per gram (mcg/g)				
median (inter-quartile range (Q1-Q3))				
Change at Week 8 (n= 167, 161, 163)	0.0 (-44.8 to 72.0)	0.0 (-35.0 to 48.5)	-1.4 (-52.0 to 30.9)	
Change at Week 24 (n= 166 161, 161)	2.2 (-45.3 to 139.9)	-0.8 (-47.9 to 35.1)	-2.3 (-65.5 to 25.5)	
Change at Week 44 (n= 166, 159, 160)	0.8 (-34.2 to 177.4)	-1.9 (-54.4 to 35.1)	-9.1 (-101.6 to 7.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Study: Change from Maintenance Baseline in Fecal Calprotectin Concentration at Weeks 8, 24, and 44

End point title	Maintenance Study: Change from Maintenance Baseline in Fecal Calprotectin Concentration at Weeks 8, 24, and 44

End point description:

Change from Maintenance baseline in fecal calprotectin concentration at Weeks 8, 24, and 44 were reported. Subjects who had a prohibited change in concomitant UC medication or an ostomy or colectomy, or used a rescue medication after clinical flare, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the Week 44 had their Week 0 value of the induction study carried forward from the time of the event onward. Subjects who had a missing fecal calprotectin value at the designated analysis timepoint had their last value carried forward. PEAS consisted of all subjects who were in clinical response to IV ustekinumab induction and were randomized at Week 0 of the maintenance study to ustekinumab 90 mg SC q8w, ustekinumab 90 mg SC q12w, or placebo SC. Here, n (number of subjects analyzed) signifies subjects who were analyzed for this OM at specified timepoint.

End point type	Secondary

End point timeframe:
Baseline, Weeks 8, 24, and 44

End point values	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	168	160	161	
Units: milligram per kilogram (mg/kg)				
arithmetic mean (inter-quartile range (Q1-Q3))				
Change at Week 8 (n= 168, 160, 161)	0.0 (-0.158 to 557.0)	-18.5 (-368.5 to 225.5)	-31.0 (-380.0 to 205.0)	
Change at Week 24 (n= 165, 160, 159)	125.0 (-97.0 to 1223.0)	-31.5 (-413.5 to 385.0)	-46.0 (-530.0 to 318.0)	
Change at Week 44 (n= 164, 158, 159)	229.5 (-102.5 to 1387.0)	-37.5 (-476.0 to 274.0)	-85.0 (-742.0 to 166.0)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Up to Week 220

Adverse event reporting additional description:

The safety analysis set included subjects who received at least 1 dose of studyagent, including partial dose, according to actual treatment received.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Induction Study(IS): Placebo Intravenous (IV)

Reporting group description:

Subjects received single dose of placebo as intravenous (IV) infusion at Week 0. Participants with clinical response at Week (W) 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received weight-range based dose of ustekinumab approximating 6 mg/kg IV + placebo SC at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Ustekinumab 130 milligram (mg) IV

Reporting group description:

Subjects received single dose of ustekinumab 130 mg as IV infusion at Week 0. Subjects with clinical response at Week 8 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Ustekinumab Nonresponders at Week 8

Reporting group description:

Subjects who did not achieve clinical response to ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 and received a single dose of ustekinumab 90 mg SC along with matching placebo IV (to maintain the blind). Subjects with clinical response at Week 16 (that is, delayed responders) were eligible to enter Maintenance study, but were not be randomized. Included data from Week 8 onward through the final safety visit.

Reporting group title	Maintenance study(MS): Placebo Subcutaneous (SC)

Reporting group description:

Subjects in clinical response (at Week 8 or Week 16) to Induction treatment with single IV infusion of Ustekinumab who were randomized to receive placebo subcutaneously, beginning Week 0 of Maintenance study through Week 44.

Reporting group title	MS: Ustekinumab 90mg SC every 12 weeks (q12w)

Reporting group description:

Subjects who were randomized to receive ustekinumab (ie, 130 mg IV or approximately 6 mg/kg IV) at Week 0 of the induction study and were in clinical response at induction Week 8 and subjects who were randomized to receive placebo at Week 0 of the induction study and were not in clinical response at induction Week 8 but were in clinical response at induction Week 16 after receiving a dose of IV ustekinumab (approximately 6 mg/kg) at induction Week 8 (placebo to ustekinumab 6 mg/kg IV) were randomized to receive ustekinumab 90 mg SC every 12 weeks (q12w) beginning at Week 0 of maintenance study through Week 44.

Reporting group title	IS: Ustekinumab approximately 6mg/kg IV

Reporting group description:

Subjects received weight-range based dose of ustekinumab approximating 6 milligram per kilogram (mg/kg) (ustekinumab 260 mg [body weight <=55 kg], 390 mg [body weight >55 kg but <=85 kg] and 520 mg [body weight >85 kg]), as IV infusion at Week 0. Subjects with clinical response at Week 8

were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 8 received 1 dose of ustekinumab 90 mg SC+ placebo IV at Week 8. At Week 16, subjects who did not achieve clinical response at Week 8 were re-evaluated for clinical response. Subjects with clinical response at Week 16 were eligible to enter the maintenance study. Subjects who did not achieve clinical response at Week 16 were not eligible to enter the maintenance study and had a safety follow-up visit up to 20 weeks after their last dose of study agent.

Reporting group title	IS: Placebo-Nonresponders at Week 8

Reporting group description:

Subjects who did not achieve clinical response to placebo IV at Week 8 and received a single IV infusion of ustekinumab approximating 6 mg/kg at Week 8. Included data from Week 8 onward through the final safety visit.

Reporting group title	MS: Ustekinumab 90mg SC every 8 weeks (q8w)

Reporting group description:

Subjects who were randomized to receive ustekinumab (ie, 130 mg IV or approximately 6 mg/kg IV) at Week 0 of the induction study and were in clinical response at induction Week 8 and subjects who were randomized to receive placebo at Week 0 of the induction study and were not in clinical response at induction Week 8 but were in clinical response at induction Week 16 after receiving a dose of IV ustekinumab (approximately 6 mg/kg) at induction Week 8 (placebo to ustekinumab 6 mg/kg IV) were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w), beginning at Week 0 of maintenance study through Week 44.

Reporting group title	Long Term Extension (LTE): Placebo SC

Reporting group description:

Subjects who were randomized to receive placebo SC in the maintenance study and received placebo SC at the first dosing visit (Week 48) of long term extension (LTE).

Reporting group title	LTE: Placebo SC to Ustekinumab SC 90 mg q8w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Reporting group title	LTE: Ustekinumab 90 mg SC q12w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 12 weeks (q12w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Reporting group title	MS: Ustekinumab Delayed Responders(IS) to UST 90mg SC q8w

Reporting group description:

Subjects who were delayed responders to ustekinumab induction (were not in clinical response to induction treatment ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 but were in clinical response at Week 16) received ustekinumab 90 mg SC every 8 weeks, beginning at Week 0 of maintenance study through Week 44 (non-randomized subjects).

Reporting group title	MS: Placebo IV (IS – Responders) to Placebo SC

Reporting group description:

Subjects with clinical response to Induction Week 0 treatment with placebo IV received placebo SC, beginning at Week 0 of maintenance study through Week 44 (non-randomized subjects).

Reporting group title	LTE: Ustekinumab 90 mg SC q8w to 90 mg SC q8w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC q8w in the maintenance study and had a sham dose adjustment to ustekinumab 90 mg SC q8w during the LTE.

Reporting group title	LTE: Ustekinumab 90 mg SC q12w to 90 mg SC q8w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC q12w in the maintenance study and had a dose adjustment to ustekinumab 90 mg SC q8w during the LTE.

Reporting group title	LTE: Ustekinumab 90 mg SC q8w

Reporting group description:

Subjects who were randomized to receive ustekinumab 90 mg SC every 8 weeks (q8w) in the maintenance study and received ustekinumab 90 mg SC at the first dosing visit (Week 48) of the LTE.

Reporting group title	LTE: Placebo IV (IS – Responders) to Placebo SC

Reporting group description:

Subjects with clinical response to Induction Week 0 treatment with placebo IV received placebo SC in the maintenance study and the LTE through Week 200 (non-randomized subjects).

Reporting group title	LTE: Ustekinumab Delayed Responders (IS) to UST 90mg SC q8w

Reporting group description:

Subjects who were delayed responders to ustekinumab induction (were not in clinical response to induction treatment ustekinumab (130 mg or approximately 6 mg/kg [IV]) at Week 8 but were in clinical response at Week 16) received ustekinumab 90 mg SC q8w in the maintenance study and the LTE through Week 200 (non-randomized subjects).

Serious adverse events	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab Nonresponders at Week 8
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 319 (6.90%)	12 / 321 (3.74%)	12 / 233 (5.15%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Adenoma			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Papilloma of Breast			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Adenoma			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenoma			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 Papilloma			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis Cancer			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 319 (0.00%)	2 / 321 (0.62%)	0 / 233 (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
Pleurisy			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Eosinophilia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Injury			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Jaw Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Radius Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic Fracture			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (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
Cognitive Disorder			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (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
Epilepsy			

subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Dysfunction			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (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
Optic Neuritis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (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
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness Unilateral			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal Fissure			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Anorectal Disorder			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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	11 / 319 (3.45%)	4 / 321 (1.25%)	4 / 233 (1.72%)
occurrences causally related to treatment / all	0 / 12	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Fibrosis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudopolyposis			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 Disorder			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Rash			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (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 and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 Kidney Disease			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis Chronic			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Enthesopathy			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 Protrusion			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Appendicitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Complicated Appendicitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 Infection			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human Herpesvirus 6 Infection			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Herpes			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Inflammatory Disease			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital Cellulitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Abscess			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (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
Pneumonia Legionella			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
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 Viral			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingo-Oophoritis			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (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
Tooth Abscess			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	IS: Ustekinumab approximately 6mg/kg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 175 (9.71%)	13 / 172 (7.56%)	11 / 320 (3.44%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Adenoma			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Papilloma of Breast			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Lentigo Maligna			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Adenoma			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Pituitary Tumour Benign			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenoma			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 Papilloma			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Testis Cancer			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	2 / 320 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Vasculitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Eosinophilia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Injury			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic Fracture			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Dysfunction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic Neuritis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 175 (0.00%)	2 / 172 (1.16%)	0 / 320 (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
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Deafness Unilateral			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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

Anal Fissure			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal Disorder			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Colitis Ulcerative			
subjects affected / exposed	8 / 175 (4.57%)	1 / 172 (0.58%)	4 / 320 (1.25%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Enterovesical Fistula			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Fibrosis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatitis Acute			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudopolyposis			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 Disorder			

subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Calculus Bladder			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 Kidney Disease			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis Chronic			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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			
Enthesopathy			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 Protrusion			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Osteoarthritis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Appendicitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Cystitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 / 175 (0.00%)	2 / 172 (1.16%)	0 / 320 (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
Cytomegalovirus Infection			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human Herpesvirus 6 Infection			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Listeriosis			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Herpes			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Inflammatory Disease			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital Cellulitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Abscess			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (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
Pneumonia			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
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 Viral			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (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
Salpingitis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingo-Oophoritis			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Abscess			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Metabolic Decompensation			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	IS: Placebo-Nonresponders at Week 8	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	Long Term Extension (LTE): Placebo SC
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 184 (3.80%)	15 / 176 (8.52%)	6 / 115 (5.22%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Adenoma			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Papilloma of Breast			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Adenoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenoma			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 Papilloma			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis Cancer			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 184 (0.00%)	2 / 176 (1.14%)	0 / 115 (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

General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Eosinophilia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Meniscus Injury			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic Fracture			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Dysfunction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic Neuritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness Unilateral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal Fissure			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal Disorder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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	5 / 184 (2.72%)	2 / 176 (1.14%)	3 / 115 (2.61%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Fibrosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudopolyposis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 Disorder			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Pyoderma Gangrenosum			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 Kidney Disease			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis Chronic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	1 / 184 (0.54%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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			
Enthesopathy			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 Protrusion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
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 Infection			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	1 / 184 (0.54%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human Herpesvirus 6 Infection			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Herpes			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Inflammatory Disease			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital Cellulitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Perirectal Abscess			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Abscess			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 184 (0.54%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Legionella			

subjects affected / exposed	1 / 184 (0.54%)	0 / 176 (0.00%)	0 / 115 (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
Pneumonia Viral			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (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
Salpingo-Oophoritis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Abscess			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LTE: Placebo SC to Ustekinumab SC 90 mg q8w	LTE: Ustekinumab 90 mg SC q12w	MS: Ustekinumab Delayed Responders(IS) to UST 90mg SC q8w
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 56 (14.29%)	13 / 141 (9.22%)	11 / 157 (7.01%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Adenoma			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Papilloma of Breast			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Adenoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			

subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Papilloma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis Cancer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchiectasis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Eosinophilia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Suicidal Ideation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle Fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Bladder Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Fibula Fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Tibia Fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Traumatic Fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Pericarditis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Dysfunction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic Neuritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness Unilateral			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal Fissure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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	2 / 56 (3.57%)	1 / 141 (0.71%)	7 / 157 (4.46%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Enteritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Fibrosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Pseudopolyposis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Vomiting			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 Disorder			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 Kidney Disease			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Glomerulonephritis Chronic			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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			
Enthesopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 Protrusion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Sacroiliitis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Appendicitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (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
Cytomegalovirus Colitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 Infection			

subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 Salmonella			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human Herpesvirus 6 Infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (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
Influenza			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Herpes			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Inflammatory Disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital Cellulitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	1 / 157 (0.64%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Legionella			

subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
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 Viral			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingo-Oophoritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			

subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MS: Placebo IV (IS – Responders) to Placebo SC	LTE: Ustekinumab 90 mg SC q8w to 90 mg SC q8w	LTE: Ustekinumab 90 mg SC q12w to 90 mg SC q8w
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 103 (7.77%)	3 / 37 (8.11%)	6 / 64 (9.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Adenoma			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Papilloma of Breast			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Adenoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 Papilloma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis Cancer			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (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
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Eosinophilia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (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
Mental Status Changes			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 103 (0.00%)	1 / 37 (2.70%)	0 / 64 (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
Injury, poisoning and procedural complications			

Ankle Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (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
Jaw Fracture			
subjects affected / exposed	0 / 103 (0.00%)	1 / 37 (2.70%)	0 / 64 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic Fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Dysfunction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic Neuritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (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
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness Unilateral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal Fissure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal Disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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	3 / 103 (2.91%)	1 / 37 (2.70%)	3 / 64 (4.69%)
occurrences causally related to treatment / all	3 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Fibrosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudopolyposis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 Disorder			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 Kidney Disease			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis Chronic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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			
Enthesopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (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
Cellulitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 Infection			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 Salmonella			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human Herpesvirus 6 Infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Herpes			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Inflammatory Disease			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital Cellulitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
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 Viral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingo-Oophoritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LTE: Ustekinumab 90 mg SC q8w	LTE: Placebo IV (IS – Responders) to Placebo SC	LTE: Ustekinumab Delayed Responders (IS) to UST 90mg SC q8w
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 143 (10.49%)	10 / 73 (13.70%)	14 / 116 (12.07%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Adenoma			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Papilloma of Breast			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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 Adenoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 Papilloma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis Cancer			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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
Haemorrhage			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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

General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			

subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Hyperventilation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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
Pulmonary Eosinophilia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Injury			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Traumatic Fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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
Myocardial Infarction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Dysfunction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic Neuritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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
Autoimmune Haemolytic Anaemia			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness Unilateral			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal Fissure			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal Disorder			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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	5 / 143 (3.50%)	4 / 73 (5.48%)	2 / 116 (1.72%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Fibrosis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudopolyposis			

subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Disorder			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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 Kidney Disease			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis Chronic			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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			
Enthesopathy			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 Protrusion			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Osteoarthritis			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 / 143 (0.00%)	1 / 73 (1.37%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 Infection			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Human Herpesvirus 6 Infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Listeriosis			

subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Neutropenic Sepsis			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Oral Herpes			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Pelvic Inflammatory Disease			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Periorbital Cellulitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Legionella			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
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 Viral			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingo-Oophoritis			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (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
Subcutaneous Abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Abscess			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	0 / 116 (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			
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Induction Study(IS): Placebo Intravenous (IV)	IS: Ustekinumab 130 milligram (mg) IV	IS: Ustekinumab Nonresponders at Week 8
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 319 (28.53%)	100 / 321 (31.15%)	30 / 233 (12.88%)
Vascular disorders			
Hypertension			
subjects affected / exposed	5 / 319 (1.57%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	7	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 319 (1.57%)	6 / 321 (1.87%)	1 / 233 (0.43%)
occurrences (all)	5	6	1
Influenza Like Illness			
subjects affected / exposed	2 / 319 (0.63%)	2 / 321 (0.62%)	1 / 233 (0.43%)
occurrences (all)	2	2	1
Injection Site Erythema			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences (all)	0	0	1
Injection Site Swelling			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	6 / 319 (1.88%)	4 / 321 (1.25%)	0 / 233 (0.00%)
occurrences (all)	6	4	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 319 (0.94%)	4 / 321 (1.25%)	0 / 233 (0.00%)
occurrences (all)	3	4	0
Oropharyngeal Pain			

subjects affected / exposed	1 / 319 (0.31%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 319 (1.25%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	4	1	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	2 / 319 (0.63%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	2	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	2 / 319 (0.63%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	2	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	1	0	0
Blood Phosphorus Decreased			
subjects affected / exposed	1 / 319 (0.31%)	1 / 321 (0.31%)	1 / 233 (0.43%)
occurrences (all)	1	1	1
Stool Analysis Abnormal			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	0	1	0
Heat Illness			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			

subjects affected / exposed	1 / 319 (0.31%)	2 / 321 (0.62%)	0 / 233 (0.00%)
occurrences (all)	1	2	0
Headache			
subjects affected / exposed	14 / 319 (4.39%)	22 / 321 (6.85%)	2 / 233 (0.86%)
occurrences (all)	17	24	2
Migraine			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 319 (3.45%)	7 / 321 (2.18%)	1 / 233 (0.43%)
occurrences (all)	11	10	1
Leukopenia			
subjects affected / exposed	1 / 319 (0.31%)	2 / 321 (0.62%)	1 / 233 (0.43%)
occurrences (all)	1	2	1
Neutropenia			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 319 (0.00%)	2 / 321 (0.62%)	1 / 233 (0.43%)
occurrences (all)	0	2	1
Abdominal Pain			
subjects affected / exposed	9 / 319 (2.82%)	8 / 321 (2.49%)	0 / 233 (0.00%)
occurrences (all)	9	9	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 319 (0.00%)	4 / 321 (1.25%)	2 / 233 (0.86%)
occurrences (all)	0	4	2
Colitis Ulcerative			

subjects affected / exposed	8 / 319 (2.51%)	5 / 321 (1.56%)	3 / 233 (1.29%)
occurrences (all)	8	5	3
Constipation			
subjects affected / exposed	1 / 319 (0.31%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	1 / 319 (0.31%)	3 / 321 (0.93%)	0 / 233 (0.00%)
occurrences (all)	1	3	0
Frequent Bowel Movements			
subjects affected / exposed	0 / 319 (0.00%)	3 / 321 (0.93%)	0 / 233 (0.00%)
occurrences (all)	0	4	0
Nausea			
subjects affected / exposed	7 / 319 (2.19%)	8 / 321 (2.49%)	3 / 233 (1.29%)
occurrences (all)	7	8	3
Rectal Haemorrhage			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 319 (0.31%)	3 / 321 (0.93%)	3 / 233 (1.29%)
occurrences (all)	1	3	3
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	3 / 319 (0.94%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	3	1	0
Eczema			
subjects affected / exposed	5 / 319 (1.57%)	1 / 321 (0.31%)	1 / 233 (0.43%)
occurrences (all)	5	2	1
Papule			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	4 / 319 (1.25%)	8 / 321 (2.49%)	0 / 233 (0.00%)
occurrences (all)	4	8	0
Rash			
subjects affected / exposed	1 / 319 (0.31%)	3 / 321 (0.93%)	2 / 233 (0.86%)
occurrences (all)	1	3	3
Skin Lesion			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 319 (0.94%)	4 / 321 (1.25%)	2 / 233 (0.86%)
occurrences (all)	3	4	2
Back Pain			
subjects affected / exposed	4 / 319 (1.25%)	2 / 321 (0.62%)	1 / 233 (0.43%)
occurrences (all)	5	2	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	1	0	0
Covid-19			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	2 / 319 (0.63%)	2 / 321 (0.62%)	0 / 233 (0.00%)
occurrences (all)	2	2	0
Herpes Zoster			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 319 (0.00%)	2 / 321 (0.62%)	2 / 233 (0.86%)
occurrences (all)	0	2	2
Laryngitis			

subjects affected / exposed	1 / 319 (0.31%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	9 / 319 (2.82%)	13 / 321 (4.05%)	1 / 233 (0.43%)
occurrences (all)	9	13	1
Oral Herpes			
subjects affected / exposed	5 / 319 (1.57%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	5	1	0
Pharyngitis			
subjects affected / exposed	1 / 319 (0.31%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	2	1	0
Rhinitis			
subjects affected / exposed	0 / 319 (0.00%)	3 / 321 (0.93%)	1 / 233 (0.43%)
occurrences (all)	0	3	1
Sinusitis			
subjects affected / exposed	1 / 319 (0.31%)	5 / 321 (1.56%)	1 / 233 (0.43%)
occurrences (all)	1	5	1
Tonsillitis			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 319 (1.25%)	6 / 321 (1.87%)	5 / 233 (2.15%)
occurrences (all)	6	6	5
Urinary Tract Infection			
subjects affected / exposed	0 / 319 (0.00%)	3 / 321 (0.93%)	0 / 233 (0.00%)
occurrences (all)	0	3	0
Viral Infection			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 319 (0.00%)	1 / 321 (0.31%)	0 / 233 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Iron Deficiency			

subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	1 / 233 (0.43%)
occurrences (all)	0	0	1
Vitamin D Deficiency			
subjects affected / exposed	0 / 319 (0.00%)	0 / 321 (0.00%)	0 / 233 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Maintenance study(MS): Placebo Subcutaneous (SC)	MS: Ustekinumab 90mg SC every 12 weeks (q12w)	IS: Ustekinumab approximately 6mg/kg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	121 / 175 (69.14%)	93 / 172 (54.07%)	103 / 320 (32.19%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 175 (0.00%)	4 / 172 (2.33%)	0 / 320 (0.00%)
occurrences (all)	0	4	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 175 (2.29%)	4 / 172 (2.33%)	8 / 320 (2.50%)
occurrences (all)	6	4	8
Influenza Like Illness			
subjects affected / exposed	4 / 175 (2.29%)	2 / 172 (1.16%)	1 / 320 (0.31%)
occurrences (all)	4	4	1
Injection Site Erythema			
subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences (all)	1	1	0
Injection Site Swelling			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	7 / 175 (4.00%)	1 / 172 (0.58%)	6 / 320 (1.88%)
occurrences (all)	7	1	8
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 175 (2.86%)	2 / 172 (1.16%)	3 / 320 (0.94%)
occurrences (all)	7	3	3
Oropharyngeal Pain			

subjects affected / exposed	5 / 175 (2.86%)	4 / 172 (2.33%)	8 / 320 (2.50%)
occurrences (all)	7	4	8
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 175 (1.14%)	3 / 172 (1.74%)	0 / 320 (0.00%)
occurrences (all)	2	3	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	4 / 175 (2.29%)	5 / 172 (2.91%)	6 / 320 (1.88%)
occurrences (all)	5	5	7
Aspartate Aminotransferase Increased			
subjects affected / exposed	4 / 175 (2.29%)	5 / 172 (2.91%)	3 / 320 (0.94%)
occurrences (all)	5	6	3
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	2 / 320 (0.63%)
occurrences (all)	1	1	2
Blood Phosphorus Decreased			
subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	1 / 320 (0.31%)
occurrences (all)	1	1	1
Stool Analysis Abnormal			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 175 (0.00%)	2 / 172 (1.16%)	2 / 320 (0.63%)
occurrences (all)	0	2	2
Heat Illness			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			

subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	4 / 320 (1.25%)
occurrences (all)	0	0	4
Headache			
subjects affected / exposed	7 / 175 (4.00%)	11 / 172 (6.40%)	13 / 320 (4.06%)
occurrences (all)	7	22	16
Migraine			
subjects affected / exposed	3 / 175 (1.71%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences (all)	3	1	0
Tremor			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 175 (6.86%)	7 / 172 (4.07%)	8 / 320 (2.50%)
occurrences (all)	13	8	8
Leukopenia			
subjects affected / exposed	3 / 175 (1.71%)	2 / 172 (1.16%)	5 / 320 (1.56%)
occurrences (all)	5	2	5
Neutropenia			
subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	1 / 320 (0.31%)
occurrences (all)	3	1	1
Eye disorders			
Cataract			
subjects affected / exposed	1 / 175 (0.57%)	2 / 172 (1.16%)	1 / 320 (0.31%)
occurrences (all)	1	3	1
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	4 / 175 (2.29%)	2 / 172 (1.16%)	0 / 320 (0.00%)
occurrences (all)	4	2	0
Abdominal Pain			
subjects affected / exposed	4 / 175 (2.29%)	6 / 172 (3.49%)	5 / 320 (1.56%)
occurrences (all)	9	6	5
Abdominal Pain Upper			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences (all)	1	0	1
Colitis Ulcerative			

subjects affected / exposed	48 / 175 (27.43%)	19 / 172 (11.05%)	5 / 320 (1.56%)
occurrences (all)	57	23	5
Constipation			
subjects affected / exposed	6 / 175 (3.43%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences (all)	6	0	1
Diarrhoea			
subjects affected / exposed	2 / 175 (1.14%)	5 / 172 (2.91%)	1 / 320 (0.31%)
occurrences (all)	2	5	2
Frequent Bowel Movements			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	1 / 320 (0.31%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	4 / 175 (2.29%)	4 / 172 (2.33%)	7 / 320 (2.19%)
occurrences (all)	4	5	7
Rectal Haemorrhage			
subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	5 / 175 (2.86%)	1 / 172 (0.58%)	4 / 320 (1.25%)
occurrences (all)	5	1	9
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 175 (0.00%)	2 / 172 (1.16%)	2 / 320 (0.63%)
occurrences (all)	0	2	4
Eczema			
subjects affected / exposed	5 / 175 (2.86%)	0 / 172 (0.00%)	2 / 320 (0.63%)
occurrences (all)	5	0	2
Papule			
subjects affected / exposed	2 / 175 (1.14%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	2	0	0
Pruritus			

subjects affected / exposed	4 / 175 (2.29%)	1 / 172 (0.58%)	3 / 320 (0.94%)
occurrences (all)	4	1	3
Rash			
subjects affected / exposed	6 / 175 (3.43%)	6 / 172 (3.49%)	4 / 320 (1.25%)
occurrences (all)	7	8	6
Skin Lesion			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	1 / 320 (0.31%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	17 / 175 (9.71%)	16 / 172 (9.30%)	6 / 320 (1.88%)
occurrences (all)	18	18	6
Back Pain			
subjects affected / exposed	7 / 175 (4.00%)	1 / 172 (0.58%)	4 / 320 (1.25%)
occurrences (all)	8	1	4
Infections and infestations			
Bronchitis			
subjects affected / exposed	6 / 175 (3.43%)	5 / 172 (2.91%)	2 / 320 (0.63%)
occurrences (all)	6	5	2
Covid-19			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 175 (0.00%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	5 / 175 (2.86%)	5 / 172 (2.91%)	1 / 320 (0.31%)
occurrences (all)	5	6	1
Herpes Zoster			
subjects affected / exposed	4 / 175 (2.29%)	0 / 172 (0.00%)	2 / 320 (0.63%)
occurrences (all)	4	0	2
Influenza			
subjects affected / exposed	8 / 175 (4.57%)	5 / 172 (2.91%)	1 / 320 (0.31%)
occurrences (all)	9	5	1
Laryngitis			

subjects affected / exposed	1 / 175 (0.57%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	28 / 175 (16.00%)	31 / 172 (18.02%)	18 / 320 (5.63%)
occurrences (all)	39	45	18
Oral Herpes			
subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	3 / 320 (0.94%)
occurrences (all)	1	2	4
Pharyngitis			
subjects affected / exposed	2 / 175 (1.14%)	3 / 172 (1.74%)	0 / 320 (0.00%)
occurrences (all)	2	3	0
Rhinitis			
subjects affected / exposed	2 / 175 (1.14%)	2 / 172 (1.16%)	1 / 320 (0.31%)
occurrences (all)	2	2	1
Sinusitis			
subjects affected / exposed	2 / 175 (1.14%)	2 / 172 (1.16%)	1 / 320 (0.31%)
occurrences (all)	2	3	1
Tonsillitis			
subjects affected / exposed	2 / 175 (1.14%)	2 / 172 (1.16%)	1 / 320 (0.31%)
occurrences (all)	2	3	1
Upper Respiratory Tract Infection			
subjects affected / exposed	8 / 175 (4.57%)	5 / 172 (2.91%)	5 / 320 (1.56%)
occurrences (all)	9	5	5
Urinary Tract Infection			
subjects affected / exposed	4 / 175 (2.29%)	3 / 172 (1.74%)	3 / 320 (0.94%)
occurrences (all)	5	7	3
Viral Infection			
subjects affected / exposed	2 / 175 (1.14%)	2 / 172 (1.16%)	0 / 320 (0.00%)
occurrences (all)	2	2	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 175 (1.14%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences (all)	2	1	0
Metabolism and nutrition disorders			
Iron Deficiency			

subjects affected / exposed	1 / 175 (0.57%)	1 / 172 (0.58%)	0 / 320 (0.00%)
occurrences (all)	1	1	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 175 (0.00%)	0 / 172 (0.00%)	0 / 320 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	IS: Placebo-Nonresponders at Week 8	MS: Ustekinumab 90mg SC every 8 weeks (q8w)	Long Term Extension (LTE): Placebo SC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 184 (14.67%)	118 / 176 (67.05%)	68 / 115 (59.13%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 184 (0.00%)	3 / 176 (1.70%)	1 / 115 (0.87%)
occurrences (all)	0	4	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 184 (0.00%)	7 / 176 (3.98%)	4 / 115 (3.48%)
occurrences (all)	0	10	4
Influenza Like Illness			
subjects affected / exposed	1 / 184 (0.54%)	2 / 176 (1.14%)	1 / 115 (0.87%)
occurrences (all)	1	2	1
Injection Site Erythema			
subjects affected / exposed	1 / 184 (0.54%)	3 / 176 (1.70%)	0 / 115 (0.00%)
occurrences (all)	1	3	0
Injection Site Swelling			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 184 (0.54%)	8 / 176 (4.55%)	2 / 115 (1.74%)
occurrences (all)	1	8	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 184 (0.00%)	7 / 176 (3.98%)	5 / 115 (4.35%)
occurrences (all)	0	8	5
Oropharyngeal Pain			

subjects affected / exposed	1 / 184 (0.54%)	7 / 176 (3.98%)	0 / 115 (0.00%)
occurrences (all)	1	8	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 184 (0.54%)	3 / 176 (1.70%)	0 / 115 (0.00%)
occurrences (all)	1	3	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 184 (0.00%)	6 / 176 (3.41%)	0 / 115 (0.00%)
occurrences (all)	0	7	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 184 (0.00%)	4 / 176 (2.27%)	0 / 115 (0.00%)
occurrences (all)	0	4	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	1	0
Blood Phosphorus Decreased			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	1	0
Stool Analysis Abnormal			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 184 (0.00%)	4 / 176 (2.27%)	0 / 115 (0.00%)
occurrences (all)	0	5	0
Heat Illness			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			

subjects affected / exposed	0 / 184 (0.00%)	3 / 176 (1.70%)	1 / 115 (0.87%)
occurrences (all)	0	3	1
Headache			
subjects affected / exposed	2 / 184 (1.09%)	18 / 176 (10.23%)	7 / 115 (6.09%)
occurrences (all)	2	27	10
Migraine			
subjects affected / exposed	0 / 184 (0.00%)	2 / 176 (1.14%)	0 / 115 (0.00%)
occurrences (all)	0	3	0
Tremor			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 184 (2.17%)	7 / 176 (3.98%)	1 / 115 (0.87%)
occurrences (all)	4	7	1
Leukopenia			
subjects affected / exposed	0 / 184 (0.00%)	3 / 176 (1.70%)	0 / 115 (0.00%)
occurrences (all)	0	3	0
Neutropenia			
subjects affected / exposed	0 / 184 (0.00%)	2 / 176 (1.14%)	1 / 115 (0.87%)
occurrences (all)	0	3	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 184 (0.00%)	5 / 176 (2.84%)	0 / 115 (0.00%)
occurrences (all)	0	5	0
Abdominal Pain			
subjects affected / exposed	0 / 184 (0.00%)	8 / 176 (4.55%)	2 / 115 (1.74%)
occurrences (all)	0	9	2
Abdominal Pain Upper			
subjects affected / exposed	0 / 184 (0.00%)	4 / 176 (2.27%)	3 / 115 (2.61%)
occurrences (all)	0	5	3
Colitis Ulcerative			

subjects affected / exposed	1 / 184 (0.54%)	16 / 176 (9.09%)	23 / 115 (20.00%)
occurrences (all)	1	18	27
Constipation			
subjects affected / exposed	1 / 184 (0.54%)	3 / 176 (1.70%)	1 / 115 (0.87%)
occurrences (all)	1	3	1
Diarrhoea			
subjects affected / exposed	0 / 184 (0.00%)	7 / 176 (3.98%)	2 / 115 (1.74%)
occurrences (all)	0	7	2
Frequent Bowel Movements			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 184 (1.63%)	6 / 176 (3.41%)	2 / 115 (1.74%)
occurrences (all)	3	9	2
Rectal Haemorrhage			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	2	0
Vomiting			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	3 / 115 (2.61%)
occurrences (all)	0	1	3
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 184 (0.00%)	3 / 176 (1.70%)	0 / 115 (0.00%)
occurrences (all)	0	3	0
Eczema			
subjects affected / exposed	0 / 184 (0.00%)	3 / 176 (1.70%)	0 / 115 (0.00%)
occurrences (all)	0	3	0
Papule			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	1 / 184 (0.54%)	2 / 176 (1.14%)	1 / 115 (0.87%)
occurrences (all)	1	2	1
Rash			
subjects affected / exposed	1 / 184 (0.54%)	6 / 176 (3.41%)	0 / 115 (0.00%)
occurrences (all)	1	6	0
Skin Lesion			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 184 (0.54%)	10 / 176 (5.68%)	6 / 115 (5.22%)
occurrences (all)	1	16	6
Back Pain			
subjects affected / exposed	0 / 184 (0.00%)	7 / 176 (3.98%)	5 / 115 (4.35%)
occurrences (all)	0	8	5
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 184 (0.54%)	6 / 176 (3.41%)	2 / 115 (1.74%)
occurrences (all)	1	6	2
Covid-19			
subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	0 / 184 (0.00%)	7 / 176 (3.98%)	1 / 115 (0.87%)
occurrences (all)	0	7	1
Herpes Zoster			
subjects affected / exposed	1 / 184 (0.54%)	2 / 176 (1.14%)	0 / 115 (0.00%)
occurrences (all)	1	2	0
Influenza			
subjects affected / exposed	0 / 184 (0.00%)	10 / 176 (5.68%)	4 / 115 (3.48%)
occurrences (all)	0	11	4
Laryngitis			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	7 / 184 (3.80%)	26 / 176 (14.77%)	17 / 115 (14.78%)
occurrences (all)	7	38	21
Oral Herpes			
subjects affected / exposed	0 / 184 (0.00%)	3 / 176 (1.70%)	0 / 115 (0.00%)
occurrences (all)	0	6	0
Pharyngitis			
subjects affected / exposed	1 / 184 (0.54%)	2 / 176 (1.14%)	1 / 115 (0.87%)
occurrences (all)	1	2	1
Rhinitis			
subjects affected / exposed	1 / 184 (0.54%)	4 / 176 (2.27%)	2 / 115 (1.74%)
occurrences (all)	1	4	2
Sinusitis			
subjects affected / exposed	0 / 184 (0.00%)	7 / 176 (3.98%)	3 / 115 (2.61%)
occurrences (all)	0	11	3
Tonsillitis			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	1 / 115 (0.87%)
occurrences (all)	0	1	1
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 184 (1.09%)	16 / 176 (9.09%)	6 / 115 (5.22%)
occurrences (all)	2	21	6
Urinary Tract Infection			
subjects affected / exposed	1 / 184 (0.54%)	2 / 176 (1.14%)	2 / 115 (1.74%)
occurrences (all)	1	2	2
Viral Infection			
subjects affected / exposed	2 / 184 (1.09%)	3 / 176 (1.70%)	2 / 115 (1.74%)
occurrences (all)	2	3	2
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Iron Deficiency			

subjects affected / exposed	0 / 184 (0.00%)	0 / 176 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Vitamin D Deficiency			
subjects affected / exposed	0 / 184 (0.00%)	1 / 176 (0.57%)	0 / 115 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	LTE: Placebo SC to Ustekinumab SC 90 mg q8w	LTE: Ustekinumab 90 mg SC q12w	MS: Ustekinumab Delayed Responders(IS) to UST 90mg SC q8w
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 56 (85.71%)	98 / 141 (69.50%)	93 / 157 (59.24%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 56 (3.57%)	5 / 141 (3.55%)	3 / 157 (1.91%)
occurrences (all)	2	5	3
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	3 / 157 (1.91%)
occurrences (all)	1	0	4
Influenza Like Illness			
subjects affected / exposed	0 / 56 (0.00%)	2 / 141 (1.42%)	0 / 157 (0.00%)
occurrences (all)	0	2	0
Injection Site Erythema			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	3 / 157 (1.91%)
occurrences (all)	0	1	4
Injection Site Swelling			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	3 / 56 (5.36%)	0 / 141 (0.00%)	5 / 157 (3.18%)
occurrences (all)	3	0	5
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 56 (8.93%)	2 / 141 (1.42%)	4 / 157 (2.55%)
occurrences (all)	5	3	4
Oropharyngeal Pain			

subjects affected / exposed	1 / 56 (1.79%)	7 / 141 (4.96%)	1 / 157 (0.64%)
occurrences (all)	1	7	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	7 / 56 (12.50%)	3 / 141 (2.13%)	1 / 157 (0.64%)
occurrences (all)	7	5	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	5 / 56 (8.93%)	1 / 141 (0.71%)	3 / 157 (1.91%)
occurrences (all)	5	2	4
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	2 / 56 (3.57%)	1 / 141 (0.71%)	2 / 157 (1.27%)
occurrences (all)	2	2	2
Blood Phosphorus Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences (all)	0	0	1
Stool Analysis Abnormal			
subjects affected / exposed	4 / 56 (7.14%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences (all)	6	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 56 (3.57%)	1 / 141 (0.71%)	1 / 157 (0.64%)
occurrences (all)	3	1	2
Heat Illness			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences (all)	2	0	1
Ligament Sprain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	1 / 157 (0.64%)
occurrences (all)	0	1	1
Nervous system disorders			
Dizziness			

subjects affected / exposed	1 / 56 (1.79%)	2 / 141 (1.42%)	2 / 157 (1.27%)
occurrences (all)	1	2	2
Headache			
subjects affected / exposed	4 / 56 (7.14%)	9 / 141 (6.38%)	9 / 157 (5.73%)
occurrences (all)	5	9	21
Migraine			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	2 / 157 (1.27%)
occurrences (all)	0	0	3
Tremor			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 56 (5.36%)	4 / 141 (2.84%)	9 / 157 (5.73%)
occurrences (all)	3	4	9
Leukopenia			
subjects affected / exposed	2 / 56 (3.57%)	3 / 141 (2.13%)	5 / 157 (3.18%)
occurrences (all)	2	4	7
Neutropenia			
subjects affected / exposed	2 / 56 (3.57%)	1 / 141 (0.71%)	4 / 157 (2.55%)
occurrences (all)	3	1	6
Eye disorders			
Cataract			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	3 / 157 (1.91%)
occurrences (all)	0	1	4
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	3 / 56 (5.36%)	2 / 141 (1.42%)	1 / 157 (0.64%)
occurrences (all)	3	2	1
Abdominal Pain			
subjects affected / exposed	1 / 56 (1.79%)	2 / 141 (1.42%)	5 / 157 (3.18%)
occurrences (all)	1	3	7
Abdominal Pain Upper			
subjects affected / exposed	2 / 56 (3.57%)	4 / 141 (2.84%)	1 / 157 (0.64%)
occurrences (all)	2	4	2
Colitis Ulcerative			

subjects affected / exposed	11 / 56 (19.64%)	34 / 141 (24.11%)	23 / 157 (14.65%)
occurrences (all)	12	40	27
Constipation			
subjects affected / exposed	1 / 56 (1.79%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	1 / 56 (1.79%)	6 / 141 (4.26%)	6 / 157 (3.82%)
occurrences (all)	1	7	6
Frequent Bowel Movements			
subjects affected / exposed	1 / 56 (1.79%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	1 / 56 (1.79%)	5 / 141 (3.55%)	5 / 157 (3.18%)
occurrences (all)	1	6	5
Rectal Haemorrhage			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	3 / 157 (1.91%)
occurrences (all)	2	0	3
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	2 / 56 (3.57%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences (all)	2	1	0
Papule			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	2	0	0
Pruritus			

subjects affected / exposed	1 / 56 (1.79%)	1 / 141 (0.71%)	2 / 157 (1.27%)
occurrences (all)	1	1	2
Rash			
subjects affected / exposed	1 / 56 (1.79%)	2 / 141 (1.42%)	2 / 157 (1.27%)
occurrences (all)	1	3	2
Skin Lesion			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 56 (7.14%)	9 / 141 (6.38%)	16 / 157 (10.19%)
occurrences (all)	5	9	19
Back Pain			
subjects affected / exposed	6 / 56 (10.71%)	7 / 141 (4.96%)	5 / 157 (3.18%)
occurrences (all)	8	8	5
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 56 (5.36%)	7 / 141 (4.96%)	6 / 157 (3.82%)
occurrences (all)	5	9	7
Covid-19			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	2 / 56 (3.57%)	4 / 141 (2.84%)	5 / 157 (3.18%)
occurrences (all)	3	4	6
Herpes Zoster			
subjects affected / exposed	0 / 56 (0.00%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	4 / 56 (7.14%)	6 / 141 (4.26%)	7 / 157 (4.46%)
occurrences (all)	4	6	7
Laryngitis			

subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	0 / 157 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	13 / 56 (23.21%)	29 / 141 (20.57%)	19 / 157 (12.10%)
occurrences (all)	28	51	20
Oral Herpes			
subjects affected / exposed	1 / 56 (1.79%)	3 / 141 (2.13%)	0 / 157 (0.00%)
occurrences (all)	1	4	0
Pharyngitis			
subjects affected / exposed	0 / 56 (0.00%)	3 / 141 (2.13%)	2 / 157 (1.27%)
occurrences (all)	0	4	2
Rhinitis			
subjects affected / exposed	2 / 56 (3.57%)	2 / 141 (1.42%)	1 / 157 (0.64%)
occurrences (all)	2	3	1
Sinusitis			
subjects affected / exposed	2 / 56 (3.57%)	5 / 141 (3.55%)	3 / 157 (1.91%)
occurrences (all)	3	7	3
Tonsillitis			
subjects affected / exposed	1 / 56 (1.79%)	3 / 141 (2.13%)	0 / 157 (0.00%)
occurrences (all)	1	6	0
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 56 (7.14%)	12 / 141 (8.51%)	7 / 157 (4.46%)
occurrences (all)	5	14	9
Urinary Tract Infection			
subjects affected / exposed	2 / 56 (3.57%)	0 / 141 (0.00%)	4 / 157 (2.55%)
occurrences (all)	2	0	5
Viral Infection			
subjects affected / exposed	0 / 56 (0.00%)	3 / 141 (2.13%)	1 / 157 (0.64%)
occurrences (all)	0	3	1
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 141 (0.00%)	1 / 157 (0.64%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Iron Deficiency			

subjects affected / exposed	1 / 56 (1.79%)	1 / 141 (0.71%)	1 / 157 (0.64%)
occurrences (all)	1	1	1
Vitamin D Deficiency			
subjects affected / exposed	1 / 56 (1.79%)	1 / 141 (0.71%)	0 / 157 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	MS: Placebo IV (IS – Responders) to Placebo SC	LTE: Ustekinumab 90 mg SC q8w to 90 mg SC q8w	LTE: Ustekinumab 90 mg SC q12w to 90 mg SC q8w
Total subjects affected by non-serious adverse events			
subjects affected / exposed	69 / 103 (66.99%)	27 / 37 (72.97%)	38 / 64 (59.38%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 103 (0.97%)	3 / 37 (8.11%)	1 / 64 (1.56%)
occurrences (all)	1	3	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 103 (2.91%)	1 / 37 (2.70%)	2 / 64 (3.13%)
occurrences (all)	3	2	2
Influenza Like Illness			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 103 (0.00%)	1 / 37 (2.70%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Injection Site Swelling			
subjects affected / exposed	0 / 103 (0.00%)	2 / 37 (5.41%)	0 / 64 (0.00%)
occurrences (all)	0	3	0
Pyrexia			
subjects affected / exposed	5 / 103 (4.85%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	6	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 103 (3.88%)	1 / 37 (2.70%)	2 / 64 (3.13%)
occurrences (all)	4	1	2
Oropharyngeal Pain			

subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 103 (3.88%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	4	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 103 (2.91%)	1 / 37 (2.70%)	3 / 64 (4.69%)
occurrences (all)	3	1	4
Aspartate Aminotransferase Increased			
subjects affected / exposed	4 / 103 (3.88%)	1 / 37 (2.70%)	3 / 64 (4.69%)
occurrences (all)	4	1	3
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Blood Phosphorus Decreased			
subjects affected / exposed	1 / 103 (0.97%)	1 / 37 (2.70%)	2 / 64 (3.13%)
occurrences (all)	1	1	2
Stool Analysis Abnormal			
subjects affected / exposed	0 / 103 (0.00%)	2 / 37 (5.41%)	1 / 64 (1.56%)
occurrences (all)	0	2	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Heat Illness			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	1 / 103 (0.97%)	2 / 37 (5.41%)	1 / 64 (1.56%)
occurrences (all)	1	2	1
Nervous system disorders			
Dizziness			

subjects affected / exposed	0 / 103 (0.00%)	1 / 37 (2.70%)	2 / 64 (3.13%)
occurrences (all)	0	1	2
Headache			
subjects affected / exposed	4 / 103 (3.88%)	2 / 37 (5.41%)	2 / 64 (3.13%)
occurrences (all)	4	3	2
Migraine			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Tremor			
subjects affected / exposed	1 / 103 (0.97%)	2 / 37 (5.41%)	0 / 64 (0.00%)
occurrences (all)	1	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 103 (8.74%)	1 / 37 (2.70%)	3 / 64 (4.69%)
occurrences (all)	9	1	4
Leukopenia			
subjects affected / exposed	4 / 103 (3.88%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	5	0	0
Neutropenia			
subjects affected / exposed	3 / 103 (2.91%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	3	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	2 / 64 (3.13%)
occurrences (all)	1	0	2
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain			
subjects affected / exposed	3 / 103 (2.91%)	1 / 37 (2.70%)	2 / 64 (3.13%)
occurrences (all)	3	1	2
Abdominal Pain Upper			
subjects affected / exposed	1 / 103 (0.97%)	1 / 37 (2.70%)	1 / 64 (1.56%)
occurrences (all)	1	1	1
Colitis Ulcerative			

subjects affected / exposed	25 / 103 (24.27%)	13 / 37 (35.14%)	20 / 64 (31.25%)
occurrences (all)	30	19	26
Constipation			
subjects affected / exposed	1 / 103 (0.97%)	1 / 37 (2.70%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Diarrhoea			
subjects affected / exposed	2 / 103 (1.94%)	2 / 37 (5.41%)	3 / 64 (4.69%)
occurrences (all)	2	2	3
Frequent Bowel Movements			
subjects affected / exposed	0 / 103 (0.00%)	2 / 37 (5.41%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	3 / 103 (2.91%)	1 / 37 (2.70%)	1 / 64 (1.56%)
occurrences (all)	3	1	1
Rectal Haemorrhage			
subjects affected / exposed	1 / 103 (0.97%)	3 / 37 (8.11%)	0 / 64 (0.00%)
occurrences (all)	1	3	0
Vomiting			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	4 / 103 (3.88%)	1 / 37 (2.70%)	0 / 64 (0.00%)
occurrences (all)	4	1	0
Eczema			
subjects affected / exposed	2 / 103 (1.94%)	1 / 37 (2.70%)	0 / 64 (0.00%)
occurrences (all)	2	1	0
Papule			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0
Pruritus			

subjects affected / exposed	3 / 103 (2.91%)	0 / 37 (0.00%)	2 / 64 (3.13%)
occurrences (all)	3	0	2
Rash			
subjects affected / exposed	2 / 103 (1.94%)	1 / 37 (2.70%)	1 / 64 (1.56%)
occurrences (all)	2	1	1
Skin Lesion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	9 / 103 (8.74%)	2 / 37 (5.41%)	5 / 64 (7.81%)
occurrences (all)	13	3	6
Back Pain			
subjects affected / exposed	3 / 103 (2.91%)	2 / 37 (5.41%)	3 / 64 (4.69%)
occurrences (all)	3	2	3
Infections and infestations			
Bronchitis			
subjects affected / exposed	5 / 103 (4.85%)	0 / 37 (0.00%)	2 / 64 (3.13%)
occurrences (all)	5	0	2
Covid-19			
subjects affected / exposed	0 / 103 (0.00%)	1 / 37 (2.70%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
Ear Infection			
subjects affected / exposed	0 / 103 (0.00%)	2 / 37 (5.41%)	0 / 64 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	2 / 103 (1.94%)	3 / 37 (8.11%)	0 / 64 (0.00%)
occurrences (all)	2	3	0
Herpes Zoster			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	6 / 103 (5.83%)	3 / 37 (8.11%)	3 / 64 (4.69%)
occurrences (all)	6	4	3
Laryngitis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	13 / 103 (12.62%)	12 / 37 (32.43%)	10 / 64 (15.63%)
occurrences (all)	18	14	16
Oral Herpes			
subjects affected / exposed	2 / 103 (1.94%)	2 / 37 (5.41%)	1 / 64 (1.56%)
occurrences (all)	4	2	2
Pharyngitis			
subjects affected / exposed	4 / 103 (3.88%)	2 / 37 (5.41%)	1 / 64 (1.56%)
occurrences (all)	4	3	1
Rhinitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 37 (0.00%)	1 / 64 (1.56%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	1 / 103 (0.97%)	4 / 37 (10.81%)	1 / 64 (1.56%)
occurrences (all)	1	4	1
Tonsillitis			
subjects affected / exposed	2 / 103 (1.94%)	1 / 37 (2.70%)	0 / 64 (0.00%)
occurrences (all)	2	2	0
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 103 (3.88%)	2 / 37 (5.41%)	4 / 64 (6.25%)
occurrences (all)	5	2	5
Urinary Tract Infection			
subjects affected / exposed	2 / 103 (1.94%)	3 / 37 (8.11%)	3 / 64 (4.69%)
occurrences (all)	2	3	4
Viral Infection			
subjects affected / exposed	1 / 103 (0.97%)	2 / 37 (5.41%)	0 / 64 (0.00%)
occurrences (all)	1	2	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 103 (1.94%)	0 / 37 (0.00%)	2 / 64 (3.13%)
occurrences (all)	2	0	2
Metabolism and nutrition disorders			
Iron Deficiency			

subjects affected / exposed	1 / 103 (0.97%)	2 / 37 (5.41%)	1 / 64 (1.56%)
occurrences (all)	1	2	1
Vitamin D Deficiency			
subjects affected / exposed	1 / 103 (0.97%)	0 / 37 (0.00%)	0 / 64 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	LTE: Ustekinumab 90 mg SC q8w	LTE: Placebo IV (IS – Responders) to Placebo SC	LTE: Ustekinumab Delayed Responders (IS) to UST 90mg SC q8w
Total subjects affected by non-serious adverse events			
subjects affected / exposed	105 / 143 (73.43%)	45 / 73 (61.64%)	91 / 116 (78.45%)
Vascular disorders			
Hypertension			
subjects affected / exposed	5 / 143 (3.50%)	3 / 73 (4.11%)	3 / 116 (2.59%)
occurrences (all)	5	3	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 143 (3.50%)	1 / 73 (1.37%)	2 / 116 (1.72%)
occurrences (all)	5	1	2
Influenza Like Illness			
subjects affected / exposed	4 / 143 (2.80%)	1 / 73 (1.37%)	5 / 116 (4.31%)
occurrences (all)	5	1	5
Injection Site Erythema			
subjects affected / exposed	5 / 143 (3.50%)	0 / 73 (0.00%)	3 / 116 (2.59%)
occurrences (all)	7	0	5
Injection Site Swelling			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	1 / 143 (0.70%)	2 / 73 (2.74%)	7 / 116 (6.03%)
occurrences (all)	1	4	7
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 143 (4.90%)	1 / 73 (1.37%)	4 / 116 (3.45%)
occurrences (all)	7	1	6
Oropharyngeal Pain			

subjects affected / exposed	5 / 143 (3.50%)	1 / 73 (1.37%)	3 / 116 (2.59%)
occurrences (all)	5	1	3
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 143 (1.40%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	2	0	1
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 143 (2.10%)	0 / 73 (0.00%)	4 / 116 (3.45%)
occurrences (all)	3	0	8
Aspartate Aminotransferase Increased			
subjects affected / exposed	4 / 143 (2.80%)	0 / 73 (0.00%)	3 / 116 (2.59%)
occurrences (all)	4	0	5
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Blood Phosphorus Decreased			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Stool Analysis Abnormal			
subjects affected / exposed	3 / 143 (2.10%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	3	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 143 (2.10%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences (all)	3	0	2
Heat Illness			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Ligament Sprain			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Nervous system disorders			
Dizziness			

subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	11 / 143 (7.69%)	4 / 73 (5.48%)	11 / 116 (9.48%)
occurrences (all)	15	4	14
Migraine			
subjects affected / exposed	2 / 143 (1.40%)	1 / 73 (1.37%)	2 / 116 (1.72%)
occurrences (all)	6	1	16
Tremor			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 143 (1.40%)	3 / 73 (4.11%)	4 / 116 (3.45%)
occurrences (all)	2	3	6
Leukopenia			
subjects affected / exposed	0 / 143 (0.00%)	2 / 73 (2.74%)	3 / 116 (2.59%)
occurrences (all)	0	3	4
Neutropenia			
subjects affected / exposed	2 / 143 (1.40%)	0 / 73 (0.00%)	3 / 116 (2.59%)
occurrences (all)	2	0	4
Eye disorders			
Cataract			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	5 / 143 (3.50%)	0 / 73 (0.00%)	3 / 116 (2.59%)
occurrences (all)	5	0	4
Abdominal Pain			
subjects affected / exposed	15 / 143 (10.49%)	4 / 73 (5.48%)	5 / 116 (4.31%)
occurrences (all)	24	5	5
Abdominal Pain Upper			
subjects affected / exposed	2 / 143 (1.40%)	1 / 73 (1.37%)	2 / 116 (1.72%)
occurrences (all)	2	1	2
Colitis Ulcerative			

subjects affected / exposed	37 / 143 (25.87%)	27 / 73 (36.99%)	30 / 116 (25.86%)
occurrences (all)	43	31	39
Constipation			
subjects affected / exposed	5 / 143 (3.50%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences (all)	5	0	2
Diarrhoea			
subjects affected / exposed	13 / 143 (9.09%)	4 / 73 (5.48%)	9 / 116 (7.76%)
occurrences (all)	17	4	12
Frequent Bowel Movements			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	9 / 143 (6.29%)	1 / 73 (1.37%)	5 / 116 (4.31%)
occurrences (all)	11	1	6
Rectal Haemorrhage			
subjects affected / exposed	2 / 143 (1.40%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	6 / 143 (4.20%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences (all)	7	0	2
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	2 / 143 (1.40%)	0 / 73 (0.00%)	3 / 116 (2.59%)
occurrences (all)	4	0	3
Papule			
subjects affected / exposed	0 / 143 (0.00%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	2 / 143 (1.40%)	0 / 73 (0.00%)	3 / 116 (2.59%)
occurrences (all)	2	0	4
Rash			
subjects affected / exposed	5 / 143 (3.50%)	6 / 73 (8.22%)	3 / 116 (2.59%)
occurrences (all)	5	7	3
Skin Lesion			
subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	11 / 143 (7.69%)	4 / 73 (5.48%)	10 / 116 (8.62%)
occurrences (all)	13	4	12
Back Pain			
subjects affected / exposed	7 / 143 (4.90%)	5 / 73 (6.85%)	6 / 116 (5.17%)
occurrences (all)	9	6	7
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 143 (2.80%)	0 / 73 (0.00%)	6 / 116 (5.17%)
occurrences (all)	7	0	7
Covid-19			
subjects affected / exposed	3 / 143 (2.10%)	0 / 73 (0.00%)	4 / 116 (3.45%)
occurrences (all)	3	0	4
Ear Infection			
subjects affected / exposed	4 / 143 (2.80%)	0 / 73 (0.00%)	2 / 116 (1.72%)
occurrences (all)	4	0	2
Gastroenteritis			
subjects affected / exposed	5 / 143 (3.50%)	2 / 73 (2.74%)	8 / 116 (6.90%)
occurrences (all)	5	4	9
Herpes Zoster			
subjects affected / exposed	3 / 143 (2.10%)	0 / 73 (0.00%)	5 / 116 (4.31%)
occurrences (all)	3	0	6
Influenza			
subjects affected / exposed	10 / 143 (6.99%)	6 / 73 (8.22%)	3 / 116 (2.59%)
occurrences (all)	12	6	5
Laryngitis			

subjects affected / exposed	1 / 143 (0.70%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	27 / 143 (18.88%)	5 / 73 (6.85%)	32 / 116 (27.59%)
occurrences (all)	52	10	55
Oral Herpes			
subjects affected / exposed	6 / 143 (4.20%)	4 / 73 (5.48%)	0 / 116 (0.00%)
occurrences (all)	9	6	0
Pharyngitis			
subjects affected / exposed	3 / 143 (2.10%)	3 / 73 (4.11%)	0 / 116 (0.00%)
occurrences (all)	3	3	0
Rhinitis			
subjects affected / exposed	2 / 143 (1.40%)	0 / 73 (0.00%)	1 / 116 (0.86%)
occurrences (all)	2	0	1
Sinusitis			
subjects affected / exposed	8 / 143 (5.59%)	1 / 73 (1.37%)	4 / 116 (3.45%)
occurrences (all)	15	1	5
Tonsillitis			
subjects affected / exposed	3 / 143 (2.10%)	1 / 73 (1.37%)	6 / 116 (5.17%)
occurrences (all)	4	2	6
Upper Respiratory Tract Infection			
subjects affected / exposed	17 / 143 (11.89%)	4 / 73 (5.48%)	10 / 116 (8.62%)
occurrences (all)	26	4	17
Urinary Tract Infection			
subjects affected / exposed	6 / 143 (4.20%)	1 / 73 (1.37%)	3 / 116 (2.59%)
occurrences (all)	9	1	3
Viral Infection			
subjects affected / exposed	3 / 143 (2.10%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	3	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 143 (0.00%)	1 / 73 (1.37%)	3 / 116 (2.59%)
occurrences (all)	0	1	3
Metabolism and nutrition disorders			
Iron Deficiency			

subjects affected / exposed	4 / 143 (2.80%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	4	0	0
Vitamin D Deficiency			
subjects affected / exposed	5 / 143 (3.50%)	0 / 73 (0.00%)	0 / 116 (0.00%)
occurrences (all)	6	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 July 2015	To address health authority feedback and provide additional clarifications.
20 April 2016	To address health authority requests for additional data collection as well as to address investigator feedback and to provide further clarifications on the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported