Title: A Phase IIa study to evaluate the safety and efficacy of ABX464 50 mg once daily versus Placebo in Subjects with Moderate to Severe Active Ulcerative Colitis who have failed or are intolerant to immunomodulators, Anti-TNFα, vedolizumab and/or corticosteroids

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Statistical Analysis Plan

ABX464-101

A Phase IIa study to evaluate the safety and efficacy of ABX464 50 mg once daily versus Placebo in Subjects with Moderate to Severe Active Ulcerative Colitis who have failed or are intolerant to immunomodulators, Anti-TNFα, vedolizumab and/or corticosteroids

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GLOSSARY OF ABBREVIATIONS

%CV	Coefficient of Variation
AE	Adverse Event
ALT	Alanine Transaminase (also SGPT)
AM	Arithmetic Mean
ANCOVA	Analysis of Covariance
AST	Aspartate Transaminase (also SGOT)
ATC	Anatomical Therapeutic Chemical
AUC	Area Under the Plasma Concentration Curve
AUCtau	Area Under the Plasma Concentration-time Curve calculated over one dosing interval at steady state
BLQ	Below the Limit of Quantification
BMI	Body Mass Index
BUN	Blood Urea Nitrogen
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
Cmax	Maximum observed plasma concentration
CRA	Clinical Research Associate
CS	Clinically Significant
CSR	Clinical Study Report
CTCAE	Common Toxicity Criteria Adverse Event
CV	Coefficient of Variation
DBL	Database Lock
DMP	Data Management Plan
DOB	Date of Birth
DRM	Data Review Meeting
DSMB	Data Safety Monitoring Board
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EOS	End of Study
FAS	Full Analysis Set
GGT	Gamma-Glutamyl-Transferase
GM	Geometric Mean

ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
LDH	Lactate Dehydrogenase
LLQ	Lower Limit of Quantification
LS Mean	Least Squares Mean
MCS	Mayo Clinic Score
MedDRA	Medical Dictionary for Regulatory Activities
MH	Mental Health
ml	Millilitre
N	Number of Patients
n	Number of Events
NCS	Not clinically significant
od	Once daily
PH	Physical Health
PK	Pharmacokinetics
PMS	Partial Mayo Score
PP	Per Protocol
PT	Preferred Term
QC	Quality Control
QoL	Quality of Life
RBC	Red Blood Cell
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SE	Standard Error
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
tmax	Time from dosing to the maximum observed plasma concentration
TMS	Total Mayo Score
UC	Ulcerative Colitis
WBC	White Blood Cell

WHO	World Health Organisation
WHODD	World Health Organisation Drug Dictionary

1 INTRODUCTION

1.1 GENERAL

This statistical analysis plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under Abivax Protocol ABX-464-001 and should be read in conjunction with the study protocol and electronic case report form (eCRF).

This version of the plan has been developed using the protocol Version 2.0 dated 13MAR2018 annotated eCRF Version 3.0 dated 11APR2018. Any further changes to the protocol or eCRF will be reviewed for potential impact on the SAP which will be amended if it is deemed necessary.

2 STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVE

The primary objective of the study is to evaluate the safety of ABX464 given at 50 mg once daily versus placebo in subjects with moderate to severe active ulcerative colitis who have failed or are intolerant to immunomodulators, Anti-TNFα, vedolizumab and/or corticosteroids.

2.2 SECONDARY OBJECTIVES

The secondary objectives of the study are to evaluate the effect of ABX464 compared to placebo on the following parameters, in subjects with moderate to severe active ulcerative colitis:

- Expression of IL-22 in serum and rectal/sigmoidal tissue
- miR-124 expression in whole blood (PAXgene®) and in tissue (RNA later)
- Rectal/sigmoidal infiltrates (Geboes score)
- Rectal microbiome
- Endoscopic remission
- Clinical remission and response
- Quality of Life (QoL) measured by the SF-36 questionnaire
- Pharmacokinetics parameters

3 STUDY DESIGN

3.1 OVERVIEW

This is a Phase IIa, eight-week, double-blind, placebo-controlled randomised study aimed at evaluating the safety and efficacy of ABX464 given once a day (o.d.) at 50 mg, followed by a one-month follow-up

period, in subjects with moderate to severe active ulcerative colitis (UC), who have failed or are intolerant to immunomodulators, anti-TNFα, vedolizumab and/or corticosteroids.

Eligible subjects will be recruited to up to 20 sites in France, Belgium, Poland, Germany, Austria and Hungary from Q3 2017 – Q2 2018 during the overall study period of Q2 2017 – Q3 2018. A total of 30 subjects will be randomised using a 2:1 ratio, where for every two subjects randomised to receive ABX464, one subject will be randomised to receive placebo. Thus 20 subjects will be randomised to receive ABX464 and 10 subjects will be randomised to receive placebo. Randomisation will be stratified according to concomitant treatment with corticosteroids (yes, no) and previous biologics exposure (yes, no).

The dose of 50 mg of the study drug has been selected based on the reassuring safety data accumulated on the 50 mg o.d. from previous studies and the high exposure in ABX464-NGluc (active metabolite) at this dose. A Data Safety Monitoring Board (DSMB) will meet after every three subjects are recruited in order to review the safety profile of this dose level on a regular basis and to recommend, if appropriate, the continuation of the study.

The total duration of the study will be approximately 11 weeks. Subjects will be enrolled at a screening visit, two weeks prior to the first dosing, and eligible subjects will be treated for a total of eight weeks. All subjects willing to continue with the study treatment will be able to take part in a follow-up open-label study, ABX464-102. Subjects who do not enter the open-label study will exit the study and need to perform their end of study (EoS) visit within a week after the last dosing. These subjects will be treated according to the standard of care.

3.2 Inclusion and Exclusion Criteria

To be eligible for inclusion into this study, each patient must fulfil all inclusion criteria and not violate any exclusion criteria (for the protocol under which they are entered) during screening prior to randomisation. Details of the inclusion and exclusion criteria are presented in the protocol and amendments.

3.3 Study Treatment

ABX464 or matching placebo should be administered once daily at a fixed dose of 50 mg for eight weeks.

Subjects will be orally dosed in fed condition (regular breakfast) with 240 mL of water.

A subject diary, in which the subject should report the number of capsules taken and the intake time, will be given to the subject at screening. This diary will also enable the subject to report potential discomfort or side effects s/he could experience.

For subjects receiving oral corticosteroids during the study treatment period, a tapering of steroids should start at Week 4, at a rate of prednisone or prednisone equivalent 5 mg/week for four weeks. The opportunity to perform this tapering period is left to the Investigator's discretion. A full list of permitted and prohibited concomitant medications is included in the study protocol.

3.4 Study Time Points

A screening visit will occur at Day -14, where procedures and laboratory tests are performed to determine eligibility of subjects. The Investigator will need to check the results of these procedures and if they are in line with the inclusion and exclusion criteria then the subject will be randomised. Note that the process of randomisation does not require a site visit by the subject.

At Day 0, study drug (ABX464 or its matching placebo) will be administered once a day at 50 mg for the next 56 days. Subjects will be seen at the site every week during the first month of treatment (Day 7, 14, 21 and 28) and then every two weeks during the second month (Day 42 and 56).

At Day 56, all subjects willing to carry on the study treatment will be able to take part in an open-label study (ABX464-102). In any other cases, the subjects will perform an EoS visit within a week after last dosing (Day 63). Subjects will be treated according to the standard of care since the last day of study treatment. The total duration of the study participation is 11 weeks.

Visits and visit windows will be as follows:

Visit	Day	Window
Screening	-14	± 3 days
Randomisation		
Baseline/ First dose date	0	
Treatment period	7	± 2 days
	14	± 2 days
	21	± 2 days
	28	± 2 days
	42	± 4 days
	56	± 4 days
Enter follow-up study ABX464-102 or exit study and perform EoS visit		
EoS	63	± 2 days

If more than one visit occurs within a window, the nearest to the scheduled time will be presented within the summaries.

See Section 16.1 for the Study Flow Chart.

3.5 Sample Size Considerations

The primary efficacy endpoint is the rate of subjects responding to treatment. This response rate will be compared in subjects who received ABX464 or placebo by likelihood ratio chi-squared test. For the sample size assessment, the following assumptions will be made:

- Response rate for ABX464: 0.6
- Response rate for placebo: 0.2

According to literature, the response rate for ABX464 treated subjects is expected to be between 50% and 75% while that in the placebo group is assumed to be approximately 10% to 20%.

The Type I error is defined to be one-sided 10% significance level, and the group allocation rate is 2:1 (ABX464/ placebo). If the above assumptions and these definitions hold true with a sample size of 30 subjects receiving ABX464 or placebo in a ratio of 2:1, then the study has 81% power to show a difference in response rate between the treatment groups. Power was computed using the normal approximation method. A 2:1 randomisation ratio was chosen to gain more clinical experience with ABX464 in this indication, despite the inevitable loss of power. The actual loss of power with the above assumptions is 4%.

Subjects who terminate the study prematurely will be considered failures, therefore no adjustment for dropouts is needed.

The primary safety endpoint is the rate of all treatment emergent adverse events. The above sample size is sufficient to detect an increase in general treatment emergent adverse event rate from 10% to 50% with 86% power by likelihood ratio chi-squared test at a one-sided 10% significance level.

If approximately 20 subjects receive ABX464, the study has 88% chance to detect at least 1 specific treatment emergent adverse event if the underlying rate of occurrence is 1:10. When the underlying rate of occurrence is around 1:20 the sample size of 20 subjects is sufficient to observe at least 1 such an event with a probability of 64% in the active treatment group.

3.6 RANDOMISATION

The Investigator will need to confirm subject eligibility based on procedures performed at the Day -14 visit. If a subject is eligible, they will be randomised using the eCRF and treatment numbers will be allocated immediately. The randomisation procedure does not require a site visit by the subject.

A pre-defined randomisation list will be created by SODIA, and will be centrally managed by a block of three using a 2:1 ratio, where for every two subjects randomised to receive ABX464, one subject will be randomised to receive placebo. Randomisation will be stratified according to concomitant treatment with corticosteroids (yes, no) and previous biologics exposure (yes, no).

A total of 30 patients will be randomised. A subject who prematurely exits the study for a non-drug related reason, will be replaced. In this event, an additional subject will be randomised and will receive the next treatment allocation. This may or may not be the same treatment as that of the withdrawn subject.

4 STUDY VARIABLES AND ENDPOINTS

4.1 PRIMARY VARIABLE

The primary endpoint is defined as the number of incidences of treatment-emergent adverse events (TEAE) in the ABX464 treated subjects compared to placebo.

4.2 SECONDARY EFFICACY VARIABLES

The following secondary variables will be analysed:

4.2.1 Primary Efficacy Endpoint

The proportion of subjects receiving ABX464 with clinical remission according to the Total Mayo Score (TMS) at Week 8 compared to placebo. Remission excludes friability and is based on the TMS being less than or equal to two, with no individual sub-score greater than one.

4.2.2 Other Secondary Endpoints

- The change from baseline in faecal calprotectin levels at Week 4 and Week 8 compared to placebo.
- The change from screening in TMS in subjects receiving ABX464 at Week 8 compared to placebo.
- The change from baseline in Partial Mayo Score (PMS) in subjects receiving ABX464 at Week 4 and Week 8 compared to placebo.
- The proportion of subjects achieving endoscopic remission at Week 8. Endoscopic remission is defined as a Mayo endoscopic sub-score of zero.
- The proportion of subjects achieving mucosal healing at Week 8. Mucosal healing is defined as a Mayo endoscopic sub-score of less than or equal to one.
- The proportion of subjects achieving a clinical response at Week 8. Clinical response is defined as the reduction of at least 3 points in TMS and 30% from baseline score with a decrease of at least 1 point in bleeding sub-score or an absolute bleeding sub-score of 0 or 1
- The scores and changes from baseline in mental health (MH) and physical health (PH) component summary measures of the SF-36 Questionnaire at Week 4 and Week 8.
- The number of incidences of TEAEs.
- The number of incidences of TEAEs of special interest.
- The number of incidences of TEAEs leading to investigational medicinal product (IMP) discontinuation.

- The number of incidences of specific laboratory abnormalities.

The following list includes all endpoints to be assessed by Abivax. The methods for their analysis are not included in this SAP:

- The change from screening in IL-22 expression levels in serum and rectal/sigmoidal tissue at Week 8 compared to placebo.
- The change from baseline in microRNA-124 levels in whole blood (PAXgene®) and in tissue (RNA later) at Week 4 and Week 8 compared to placebo.
- The change from screening in the histopathology/infiltrate (rectal/sigmoidal biopsies) assessed by the Geboes score at Week 8 compared to placebo.
- The change from screening in rectal microbiota using taxonomic markers at Week 8 compared to placebo.

4.3 Pharmacokinetic Variables

Pharmacokinetics will be measured via serum levels of ABX464 and will be assessed by Abivax. The methods for their analysis are not included in this SAP.

4.4 Safety Variables

Safety will be evaluated by the following:

- Adverse events
- Laboratory parameters
- Vital signs (body temperature, systolic and diastolic blood pressure, heart rate)
- Physical examination
- 12-Lead Electrocardiogram (ECG)

5 DEFINITIONS

Study Drug: Study drug is taken to mean either ABX464 or placebo.

Baseline: Baseline is defined by patient and by variable as the last non-missing value before the first dose of study drug.

Study Day: Study day is the number of days since start of treatment where the date of first dose is counted as Day 0.

Protocol Deviation: A deviation related to study inclusion or exclusion criteria, conduct of the trial, patient management or patient assessment. This refers to any change, divergence, or departure from the study design or procedures defined in the protocol. Deviations recorded by the Project Manager or

clinical research associate (CRA), or detected by data management or by statistical programming checks will be reviewed and classed as major or minor during the blind Data Review Meeting (DRM) before database lock (DBL).

Major protocol deviations: These are defined as deviations liable to bias the evaluation of the main efficacy endpoint. The following deviations will be considered as major (non-exhaustive list):

- Non-compliance with the inclusion or exclusion criteria;
- Non-compliance with the study treatment;
- Intake of prohibited medication;
- Non-compliance with time window.

6 ANALYSIS SETS

Membership of the analysis sets will be reviewed and agreed at a DRM before DBL.

6.1 FULL ANALYSIS SET

The Full Analysis Set (FAS) is defined as those patients who have received at least one dose of the study treatment, and who have at least one baseline value.

The FAS will be used for primary analyses. Patients who receive the wrong treatment in error will be analysed as randomised for efficacy analyses.

6.2 SAFETY SET

The Safety Set is defined as all patients who receive at least one dose of study treatment.

The Safety Set will be used for all safety analyses. Patients who receive the wrong treatment in error will be analysed as treated for safety analyses.

6.3 PER PROTOCOL SET

The Per Protocol (PP) set is defined as those patients of the FAS population without any major protocol deviation and who completed the study (D56).

The PP set will be used for all efficacy analyses.

7 SAFETY MONITORING

No safety monitoring reports are planned.

8 INTERIM ANALYSES

No interim analysis is planned.

9 DATA

9.1 eCRF DATA

eCRF data will be provided by Orion data management to the statistics department as SAS data sets in Orion standard format which will be used for programming the outputs to be included in the clinical study report (CSR). Populated data sets will be available when programming starts. These may contain dummy data if real data is not yet available.

9.2 EXTERNAL DATA

Laboratory parameters, pharmacokinetics, miRNA determination and biopsies will be analysed by central laboratories. Laboratory parameters will be sent to Orion by the Eurofins Central Laboratory, The Netherlands.

No other external data will be received by Orion.

9.3 RANDOMISATION LIST

The randomisation list will be uploaded to a SAS dataset following database lock.

9.4 PROGRAMMING AND DATA REVIEW

Programming of analysis datasets, tables, figures and listings will be ongoing during the data management of the study. Outputs for the DSMB will be reviewed, but no formal quality control (QC) will take place. Blind outputs may be reviewed by Abivax before DBL.

When the final data is considered clean, key listings (to be agreed) will be run and distributed to the study team for review. A blind DRM will be held to discuss the outcome of this review, the imputations for the primary endpoint and the protocol deviations. Once all data issues have been resolved and the analysis populations approved, the database will be locked. The final run of outputs and QC will then take place.

10 STATISTICAL METHODS

10.1 General Principles

All statistical methods will be based on the International Conference on Harmonisation (ICH) E9 document "Statistical Principles for Clinical Trials".

Data will be summarised by treatment group. A total column showing all patients will be included for baseline and safety summaries. Where appropriate, data will also be summarised by visit with summaries for each visit attended as scheduled and an additional summary for final (last scheduled visit or early withdrawal). The format of the summaries is defined in the shells at the end of this document.

In summary and analysis tables of continuous variables, standard descriptive statistics (N, mean, standard deviation [SD], median, minimum and maximum) will be presented. Quartiles, least squares mean (LS mean), standard error (SE) and 95% confidence interval (CI) will be presented in the statistical analysis outputs as appropriate. For PK summaries, arithmetic mean (AM), geometric mean (GM) and coefficient of variation (%CV) will be used to summarise the data. The minimum and maximum statistics will be presented in summary tables to the same number of significant figures as the original data. The mean/AM, median, LS mean, GM, CI, SD and SE will be presented to one more significant than the original data.

For numeric data which includes non-numeric values (e.g. PK data reported as below limit of quantification [BLQ] or lab results reported as < 10 or >100) the following principles will be applied when summarising the data:

- BLQ will be replaced with a value that is ½ of the lower limit of quantification (LLQ)
- Results reported as < x will be treated in the same way as BLQ with LLQ=x
- Otherwise AM, GM, SD, CI and %CV will not be calculated
- Whenever meaningful, minimum, median and maximum will be presented based on the reported data (e.g. minimum = <10, median = 20, maximum = >100)

In summary tables of categorical variables, the number of non-missing observations by category will be presented with percentages. The number of missing observations will also be presented when non-zero. Unless otherwise specified, the denominator for each percentage will be the number of non-missing observations within the column. All percentages will be presented to one decimal place.

If changes in severity for the same TEAE have been reported separately but with the same adverse event (AE) number, they will be collapsed to a single AE with maximum severity for the summary tables, but listed as reported.

Classifications of medical history, concomitant medication and adverse events will be sorted alphabetically within the summary tables.

If any laboratory assessments are repeated at the same visit, the result from the repeat assessment will be used in summaries. Both values will be listed.

Data collected on the eCRF will be presented within data listings. The data listings will be sorted by treatment group, country, centre number, patient number and visit/week/day. Treatment group will be as allocated (randomised). If any patients receive the wrong treatment this will be flagged in all listings. Visits outside the visit windows will be identified within the listings.

The date format for all output presentations will be 'ddMMMyyyy'.

All statistical analysis will be performed using SAS 9.3 or higher.

P-values will be rounded to four decimal places. P-values less than 0.0001 will be reported as <0.0001 in tables.

If any of the assumptions underlying the formal statistical methods proposed are violated during the analysis of the final data, alternative statistical methods will be used and any changes documented in the statistical methods section of the CSR, including the rationale for use.

10.2 Missing Data

There will be no imputation of missing data in this study.

10.3 Pooling of Sites

Sites will be pooled for all analyses. There will be no adjustment for centre effect or treatment by centre interaction.

10.4 Statistical Issues

There are no statistical issues.

11 STATISTICAL OUTPUT

General principles for layout of the statistical output are described in Section 10.1, including specification of the table columns, and these are illustrated for each unique table in the table shells in Section 15. For clarity and brevity in this document the phrase "by treatment group" is understood for all summaries and is not included within the text of this section.

The study analysis will be performed following database lock upon the completion of the last patient or upon its early discontinuation whichever occurs first.

11.1 Patient Disposition

A patient is considered to be a baseline failure if the patient signs the informed consent but withdraws before the screening visit. Reasons for exclusion will be recorded for patients who do not enter the study and presented in a data listing.

A patient who does not fulfil the randomisation criteria will be considered as a screen failure.

A summary of the number of screened patients, baseline failures, screening failures and reasons for screening failure will be produced for all enrolled patients (*Table 14.1.1*).

The number (%) of patients who complete or withdraw from the study and the main reason for withdrawal will be summarised for all randomised patients (*Table 14.1.2*).

The patient disposition table (*Table 14.1.3*) will summarise the following data for all randomised patients:

- The number (%) of patients in the FAS
- The number (%) of patients in the safety set
- The number (%) of patients in the PP set

A data listing presenting the eligibility for the analysis sets for each patient will also be presented.

Protocol deviations will be reviewed and classed as major or minor during the blind DRM. A listing of all patients with protocol deviations will be presented.

11.2 Patient Characteristics at Baseline

11.2.1 Demographic and Baseline Characteristics

Age will be calculated using Date of Birth (DOB) and date of informed consent and presented as age at last birthday as an integer.

Body mass index (BMI) is the patient's body weight in kilograms divided by the square of the patient's height in metres.

Age, gender, race, baseline height, baseline weight and BMI will be summarised using the FAS (*Table 14.1.4*).

11.2.2 Medical History and Current Medical Conditions

All conditions will be coded using the version of the Medical Dictionary for Regulatory Activities (MedDRA) defined in the Data Management Plan (DMP). Past medical/surgical history (conditions that stopped prior to or at the screening visit) and current medical conditions (classified as 'ongoing') will be summarised by system organ class (SOC) and preferred term (PT). The number (%) of patients reporting each condition will be presented using the FAS (*Table 14.1.5.1 and 14.1.5.2*).

11.2.3 Disease History and Characteristics

Time since UC diagnosis (years) will be summarised for the FAS (*Table 14.1.6*) and is derived as (date of informed consent - date of UC diagnosis) / 365.25. The stratification factors, concomitant treatment with corticosteroids (yes, no) and previous biologics exposure (yes, no), will be summarised within the same table.

The faecal calprotectin levels recorded at baseline will be summarised descriptively (*Table 14.1.7*). TMS, PMS and MH and PH component summary measures from the SF-36 questionnaire collected at baseline will be also be summarised descriptively within the same table. Note that the TMS encompasses the PMS (number of stools, blood in stools and severity assessment) and the endoscopy sub-score. The baseline endoscopy is performed at screening while the PMS is assessed both during the screening and the Day

0 visits. Therefore the baseline TMS value will be derived by adding the endoscopy sub-score performed at screening with the PMS done at Day 0.

The number and proportion of patients with concomitant use of medications for UC will be summarised by all categories, some of which are corticosteroid only, immunosuppressants only, combination treatment or no treatment (*Table 14.1.8*). The number and proportion of patients with prior biological failure (categorised as TNF or others / vedolizumab) will also be presented within the same table.

11.2.4 Procedures Non-Drug Therapies

All procedures/non-drug therapies recorded on the eCRF will be listed only.

11.3 Efficacy Analyses

Treatment comparisons will be ABX464 vs placebo. The main analysis set for the efficacy analyses will be the PP, and the primary analysis will be repeated for the FAS Set.

Subjects who prematurely terminate the study will be considered failures.

11.3.1 Primary Efficacy Variable

The primary efficacy endpoint, defined as the proportion of subjects receiving ABX464 with clinical remission according to the TMS at Week 8 compared to placebo, will be descriptively summarised on the PP (*Table 14.2.1.1*). Remission excludes friability and is based on the TMS being less than or equal to two, with no individual sub-score greater than one.

This response rate will be compared in subjects who received ABX464 or placebo by stratified likelihood ratio chi-square test at a one-sided 10% significance level on the PP and displayed within the same table. This table will be repeated for the FAS set (*Table 14.2.1.2*).

11.3.2 Other Secondary Efficacy Endpoints

The change from baseline to Weeks 4 and 8 in faecal calprotectin levels will be descriptively summarised and analysed using a general linear mixed (analysis of covariance (ANCOVA)) model for repeated measures fitted with treatment and stratification factors and visit as fixed effects along with a treatment-by-visit interaction term. The treatment effect (taken from the treatment-by-visit interaction terms at Week 4 and 8), 95% CI and p-values will be presented (*Table 14.2.2.1*).

The change from screening to Week 8 in TMS and the change from baseline to Week 4 and 8 in PMS will be descriptively summarised (*Tables 14.2.2.2 and 14.2.2.3*).

The number and proportion of subjects achieving endoscopic remission at Week 8 and the number and proportion of subjects achieving mucosal healing at Week 8 will be descriptively summarised (*Table 14.2.2.4*). Endoscopic remission is defined as a Mayo endoscopic sub-score of zero and mucosal healing is defined as a Mayo endoscopic sub-score of less than or equal to one.

The number and proportion of subjects achieving a clinical response at Week 8 will be descriptively summarised (*Table 14.2.2.5*). Clinical response is defined as the reduction of at least 3 points in TMS and

30% from baseline score with a decrease of at least 1 point in bleeding sub-score or an absolute bleeding sub-score of 0 or 1.

The scores and changes from baseline in the MH and PH component summary measures of the SF-36 questionnaire at Week 4 and Week 8 will be descriptively summarised (*Table 14.2.2.6*).

11.4 Safety Analyses

11.4.1 Adverse Events

All AEs will be classified using the version of the MedDRA coding dictionary specified in the DMP.

Events will be classified as treatment-emergent if they started or increased in severity on or after the first date and time of medication dosing at Day 0 and up to study closure or withdrawal date. If an event start date is partial, then the start day, month, year or stop date will be used to determine if the event is treatment-emergent. If the classification of the AE cannot be determined from the data available, then the event will be considered treatment-emergent.

An overall summary table will be presented for AEs occurring from baseline to the end of the study in the following categories (*Table 14.3.1.1*):

- Any adverse event;
- Any TEAE;
- Any serious adverse event (SAE);
- Any severe adverse event (Common Toxicity Criteria [CTC] grade 3 or 4);
- Death

The primary safety endpoint, the rate of all TEAEs will be compared between the treatments by stratified likelihood ratio chi-square test on a 10% one-sided significance level and presented in the same table.

TEAEs will be further classified as follows:

Severe TEAEs: Severity classified as 'severe' (Common Toxicity Criteria [CTC] grade 3 or 4) or missing.

Serious TEAEs: Serious classified as 'yes' or missing.

Drug-related TEAEs: Relationship to study drug classified as 'yes' or missing.

Serious drug-related TEAEs: Both serious and drug-related, as specified above.

TEAEs leading to study drug discontinuation: Action taken classified as 'permanent discontinuation'.

TEAEs overall and in each of the above classifications will be summarised separately for the following periods *(Tables 14.3.1.2.1 and 14.3.1.2.2)*:

- Period 1: Adverse event occurs or worsens from first dosing to Day 56
- Period 2: Adverse event occurs after Day 56

Summaries by SOC and PT will also be presented for TEAEs in the two periods (*Tables 14.3.1.3.1.1 and 14.3.1.3.1.2*). Similar tables will be presented for each of the classifications of treatment-emergent events above (*Tables 14.3.1.3.2.1 and 14.3.1.3.6.2*).

All AE summary tables will show the number (%) of patients having at least one event and the number of events in each treatment group and overall. Note: If a patient has multiple AEs with the same preferred term, these will be summarised once within the count for N (%) of patients, but each event will be counted within the number of reports n of each AE. Changes in severity of the same AE (if collected) will be counted only once within the number of reports n of each AE.

All adverse events (including non-treatment-emergent events) recorded on the eCRF will be listed within the data listings.

11.4.2 Laboratory Data

The following routine clinical laboratory tests will be carried out throughout the study.

- ***Haematology***: haemoglobin, haematocrit, white blood cells (WBC), neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelet count, ESR
- ***Biochemistry***: sodium, potassium, calcium, phosphate, glucose, blood urea nitrogen (BUN) /urea, creatinine, aspartate transaminase (AST), alanine transaminase (ALT), GLDH, lipase, alkaline phosphatase, gamma-glutamyl-transferase (GGT), total bilirubin, total protein, albumin, lactate dehydrogenase (LDH), CRP, T3, T4, TSH
- ***Stools***: faecal calprotectin

The absolute values of each parameter and changes from baseline will be summarised at each visit (*Tables 14.3.2.1.1 to 14.3.2.1.3*). Laboratory parameters classified as normal/ abnormal non clinically significant (NCS)/ abnormal clinically significant (CS) will be presented in a shift table showing changes from baseline to each visit for patients with at least one abnormal CS value (*Tables 14.3.2.2.1 to 14.3.2.2.3*).

If laboratory results are repeated at the same visit, the repeated result will be used in summaries (instead of the original one) provided the sample was taken within the visit window, otherwise the original result will be used. All results will be listed.

Laboratory results at unscheduled visits will be included in the listings but will not be summarised.

Pregnancy data will be listed only.

11.4.3 Vital Signs

Body temperature, systolic blood pressure, diastolic blood pressure, heart rate and weight are collected at all visits. Height is collected at Screening.

The absolute values of the vital signs and weight will be summarised at each visit (*Table 14.3.3*). Height will be summarised within the demography data.

11.4.4 Physical Examination

A physical examination will be conducted at all visits.

Physical examination data will be listed only.

11.4.5 12-Lead ECG

A 12-lead ECG will be completed at baseline, Day 28, Day 56 and EOS.

The number and percentage of the patients with Normal / Abnormal NCS / Abnormal CS ECG results will be summarised at each visit (*Table 14.3.4.1*). A shift table will be presented, for patients with at least one Abnormal CS value, showing changes from baseline to each visit (*Tables 14.3.4.2*).

11.5 Study Drug Exposure and Compliance

Number of dose intakes and study drug exposure (days) will be summarised using descriptive statistics for the FAS *(Table 14.3.5)*.

Treatment exposure is the number of days during the treatment period that the patient was exposed to the study treatment and is calculated as (date of last dose) – (date of first dose) + 1.

11.6 Prior and Concomitant Medication

All medications taken by patients on entry to the study or during the study will be recorded in the eCRF. Medications will be classified using the version of the World Health Organisation Drug Dictionary (WHODD) coding dictionary defined in the DMP. The Anatomical Therapeutic Chemical (ATC) Classification and WHO-DRUG PT will be used to list and summarise the data.

Prior medications are defined as all medications that started and stopped before date of first dose. Only medications where the stop date is prior to date of first dose will be considered prior. If the stop date is unknown or incomplete and the medications cannot definitely be considered as stopped prior to date of first dose then the medications will be considered as concomitant medications.

Concomitant medications are defined as all medications that started on or after date of first dose.

The number (%) of patients reporting the use of any prior medications and the number (%) of patients taking each drug by ATC classification (1st, 2nd and 4th levels) and PT will be summarised using the FAS (*Table 14.3.6.1*).

This table will be repeated for concomitant medications (*Table 14.3.6.2*).

12 VALIDATION

All tables, figures and listings will be subject to independent quality control and visual review. Unique tables will be independently programmed. Findings will be documented in a quality control form and actions taken will also be documented.

The completed form will be reviewed and signed by both programmers and by the head of biostatistics.

13 LITERATURE CITATIONS/REFERENCES

None

14 LIST OF TABLES, FIGURES AND LISTINGS

14.1 LIST OF TABLES

Demographic Data

Efficacy Data

Safety Data

Table 14.3.1.1	Summary of Adverse Events	Safety Set
Table 14.3.1.2.1	Summary of Treatment-Emergent Adverse Events: Period 1	Safety Set
Table 14.3.1.2.2	Summary of Treatment-Emergent Adverse Events: Period 2	Safety Set
Table 14.3.1.3.1.1	Treatment-Emergent Adverse Events, by SOC and PT: Period 1	Safety Set
Table 14.3.1.3.1.2	Treatment-Emergent Adverse Events, by SOC and PT: Period 2	Safety Set
Table 14.3.1.3.2.1	Severe Treatment-Emergent Adverse Events, by SOC and PT: Period 1	Safety Set
Table 14.3.1.3.2.2	Severe Treatment-Emergent Adverse Events, by SOC and PT: Period 2	Safety Set
Table 14.3.1.3.3.1	Serious Treatment-Emergent Adverse Events, by SOC and PT: Period 1	Safety Set
Table 14.3.1.3.3.2	Serious Treatment-Emergent Adverse Events, by SOC and PT: Period 2	Safety Set
Table 14.3.1.3.4.1	Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 1	Safety Set
Table 14.3.1.3.4.2	Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 2	Safety Set
Table 14.3.1.3.5.1	Serious Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 1	Safety Set
Table 14.3.1.3.5.2	Serious Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 2	Safety Set
Table 14.3.1.3.6.1	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation, by SOC and PT: Period 1	Safety Set
Table 14.3.1.3.6.2	Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation, by SOC and PT: Period 2	Safety Set
Table 14.3.1.3.7.1	Treatment-Emergent Adverse Events, by Intensity and SOC and PT: Period 1	Safety Set
Table 14.3.1.3.7.2	Treatment-Emergent Adverse Events, by Intensity and SOC and PT: Period 2	Safety Set
Table 14.3.2.1.1	Summary of Haematology Parameters	Safety Set
Table 14.3.2.1.2	Summary of Biochemistry Parameters	Safety Set
Table 14.3.2.1.3	Summary of Stool Results	Safety Set
Table 14.3.2.2.1	Shift Table of Haematology Parameters	Safety Set

Table 14.3.2.2.2	Shift Table of Biochemistry Parameters	Safety Set
Table 14.3.2.2.3	Shift Table of Urinalysis Parameters	Safety Set
Table 14.3.3	Vital Signs, including Weight	Safety Set
Table 14.3.4.1	12-lead Electrocardiogram	Safety Set
Table 14.3.4.2	Shift Table of 12-lead Electrocardiogram	Safety Set
Table 14.3.5	Study Drug Exposure	Full Analysis Set
Table 14.3.6.1	Prior Medications	Full Analysis Set
Table 14.3.6.2	Concomitant Medications	Full Analysis Set

14.2 List of Listings

Patient Data Listings

Listing 16.2.1	Discontinued Patients
Listing 16.2.2	Protocol Deviations
Listing 16.2.3	Analysis Datasets
Listing 16.2.4	Demographic Data
Listing 16.2.5	Study Drug Exposure and Compliance
Listing 16.2.6	Efficacy Response Data
Listing 16.2.7	Adverse Event Listing
Listing 16.2.8.1	Laboratory Measurements: Haematology
Listing 16.2.8.2	Laboratory Measurements: Biochemistry
Listing 16.2.8.3	Laboratory Measurements: Stool Results

Individual Patient Data Listings (Archive)

Listing 16.4.1	Final Status
Listing 16.4.2	Patient Visit Dates
Listing 16.4.3.1	Inclusion Criteria
Listing 16.4.3.2	Exclusion Criteria
Listing 16.4.4	Medical History
Listing 16.4.5.1	Raw Efficacy Scores: Mayo Score
Listing 16.4.5.2.1	Raw Efficacy Scores: SF-36 Questionnaire
Listing 16.4.5.2.2	Raw Efficacy Scores: SF-36 Component Summary Measures and Domain Scales

Listing 16.4.6	Study Drug Administration
Listing 16.4.7	Vital Signs
Listing 16.4.8	Physical Examination
Listing 16.4.9	12 Lead ECG
Listing 16.4.10	Prior Medications
Listing 16.4.11	Concomitant Medications
Listing 16.4.12	Procedures/Non-Drug Therapies
Listing 16.4.13	Urine Pregnancy Test
Listing 16.4.14	Laboratory Samples Collection

15 SHELLS FOR TABLES, FIGURES AND LISTINGS

The intended layouts for tables, figures and listings are presented. However, it may be appropriate for the Orion programmer to change the layouts, upon review of the data available, for completeness and clarity.

QCd output will be produced as Rich Text Format (.rtf) files for convenient inclusion in the CSR.

Subject to this, the following will apply:

- Layout will be landscape, fixed width, font size 8.
- Each output will have the heading:

  ABX464-101 (left); date ddMMMyyyy (right)
- Table headings will define the analysis set used for the summary/analysis.
- All outputs will have a footer specifying the SAS program path and filename (left); page x/y (right)
- Tables will have a footer specifying the source listing
- Figures will have a footer specifying the source table or listing
- Additional footnotes will be included where appropriate for clarification.
- Treatment group and patient number and will be included in all listings.

Table 14.1.1 Screening Failures (All Enrolled Patients)

	Total Enrolled (N=xx)
Total number of Enrolled	xx
Randomised	xx (xx.x%)
Screening failure	xx (xx.x%)
Baseline failure	xx (xx.x%)
Primary Reason for screening failure	
Inclusion criterion not met	xx (xx.x%)
Exclusion criterion	xx (xx.x%)
Withdrawal by patient	xx (xx.x%)
Other	xx (xx.x%)

The denominator for each percentage is the number of enrolled patients

Source: Listing 16.x.x
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Table 14.1.2 Study Termination and Primary Reason for Withdrawal (All Randomised Patients)

	ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Randomised	xx	xx	xx
Completed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Early withdrawal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Main reason for early withdrawal			
Investigator's decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Major protocol violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Patient's decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal of consent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

The denominator for each percentage is the number of randomised patients in the column

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Table 14.1.3 Patient Disposition (All Randomised Patients)

	ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Full Analysis Set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PP Set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Safety Set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

The denominator for each percentage is the number of randomised patients in the column

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Table 14.1.4 Demographic and Baseline Characteristics (Full Analysis Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Age (years)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Sex	N	xx	xx	xx
	Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race	N	xx	xx	xx
	White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Black	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Height (cm)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Weight (kg)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
BMI (kg/m2)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x

The denominator for each percentage is the number of non-missing observations within the column
Age was calculated using DOB and date of informed consent and presented as age at last birthday.
BMI is the patient's body weight in kilograms divided by the square of the patient's height in metres.

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Table 14.1.5.1 Medical/Surgical History (Full Analysis Set)

	ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Any medical/surgical history	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc			

The denominator for each percentage is the number of patients within the column
Medical history refers to conditions which stopped prior to or at the screening visit

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This layout also applies to:
Table 14.1.5.2 Current Medical Conditions (Full Analysis Set)

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Table 14.1.6 Disease History (Full Analysis Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Time since UC diagnosis (years)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Concomitant treatment with corticosteroids	N	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Previous biologics exposure	N	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

The denominator for each percentage is the number of non-missing observations within the column
Time since UC diagnosis (years) is calculated as date of informed consent - date of UC diagnosis) / 365.25

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Table 14.1.7 Baseline Faecal Calprotectin Levels, Total Mayo Score, Partial Mayo Score and SF-36 Component Summary Measures Score (Full Analysis Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Faecal Calprotectin Level	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Total Mayo Score	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Partial Mayo Score	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
SF-36: Mental Health Component Summary Measure	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
SF-36: Physical Health Component Summary Measure	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x

The denominator for each percentage is the number of non-missing observations within the column

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Table 14.1.8 Baseline Medication for UC and Prior Biological Failure (Full Analysis Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Concomitant Use of Medications for UC	N	xx	xx	xx
	Corticosteroid only	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Immunosuppressants only	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Combination treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Prior biological failure	N	xx	xx	xx
	TNF or others	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Vedolizumab	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

The denominator for each percentage is the number of non-missing observations within the column

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Programming note : include all possible categories for 'Concomitant Use of Medications for UC', the above list is not complete.

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Table 14.2.1.1 Analysis of Patients Achieving Clinical Remission (PP Set)

		ABX-464 (N=xx)	Placebo (N=xx)	p-value
Clinical Remission at Week 8	N	xx	xx	
	Yes	xx (xx.x%)	xx (xx.x%)	
	No	xx (xx.x%)	xx (xx.x%)	
Chi-squared test				x.xxxx

Remission excludes friability and is based on the Total Mayo Score being less than or equal to two, with no individual sub-score greater than one.

Response rate between treatments is compared using stratified likelihood ratio chi-square test at a one-sided 10% significance level.

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This layout also applies to:
Table 14.2.1.2 Analysis of Patients Achieving Clinical Remission (Full Analysis Set)

Table 14.2.2.1 Analysis of Faecal Calprotectin Levels (Per Protocol Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Treatment effect (95% CI): ABX-464 vs Placebo	p-value
Baseline	N	xx	xx		
	Mean	xx.xx	xx.xx		
	SD	xx.xx	xx.xx		
	Median	xx.xx	xx.xx		
	Minimum	xx.x	xx.x		
	Maximum	xx.x	xx.x		
Week 4	N	xx	xx		
	Mean	xx.xx	xx.xx		
	Etc				
Change from baseline to Week 4	N	xx	xx		
	Mean	xx.xx	xx.xx		
	Etc				
Week 8	N	xx	xx		
	Mean	xx.xx	xx.xx		
	Etc				
Change from baseline to Week 8	N	xx	xx		

	Mean	xx.xx	xx.xx		
	Etc				
Repeated measures ANCOVA	Treatment at Week 4			xx.x (xx.x, xx.x)	x.xxxx
	Treatment at Week 8			xx.x (xx.x, xx.x)	x.xxxx
	Concomitant use of corticosteroids				x.xxxx
	Previous biologics exposure				x.xxxx
	Visit				x.xxxx

ANCOVA model is fitted with treatment, stratification factors and visit as fixed.
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Table 14.2.2.2 Summary of Total Mayo Score (Per Protocol Set)

		ABX-464 (N=xx)	Placebo (N=xx)
Baseline	N	xx	xx
	Mean	xx.xx	xx.xx
	SD	xx.xx	xx.xx
	Median	xx.xx	xx.xx
	Minimum	xx.x	xx.x
	Maximum	xx.x	xx.x
Week 8	N	xx	xx
	Mean	xx.xx	xx.xx
	SD	xx.xx	xx.xx
	Median	xx.xx	xx.xx
	Minimum	xx.x	xx.x
	Maximum	xx.x	xx.x
Change from baseline to Week 8	N	xx	xx
	Mean	xx.xx	xx.xx
	SD	xx.xx	xx.xx
	Median	xx.xx	xx.xx
	Minimum	xx.x	xx.x
	Maximum	xx.x	xx.x

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Table 14.2.2.3 Summary of Partial Mayo Score (Per Protocol Set)

		ABX-464 (N=xx)	Placebo (N=xx)
Baseline	N	xx	xx
	Mean	xx.xx	xx.xx
	SD	xx.xx	xx.xx
	Median	xx.xx	xx.xx
	Minimum	xx.x	xx.x
	Maximum	xx.x	xx.x
Week 4	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		
Change from baseline to Week 4	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		
Week 8	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		
Change from baseline to Week 8	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		

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Table 14.2.2.4 Summary of Patients Achieving Endoscopic Remission and Mucosal Healing (Per Protocol Set)

		ABX-464 (N=xx)	Placebo (N=xx)
Endoscopic remission at Week 8	N	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)
Mucosal healing at Week 8	N	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)

Endoscopic remission is defined as a Mayo endoscopic sub-score of zero.
Mucosal healing is defined as a Mayo endoscopic sub-score of less than or equal to one.

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Table 14.2.2.5 Summary of Patients Achieving Clinical Response (Per Protocol Set)

		ABX-464 (N=xx)	Placebo (N=xx)
Clinical response at Week 8	N	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)

Clinical response is defined as the reduction of at least 3 points in TMS and 30% from baseline score with a decrease of at least 1 point in bleeding sub-score or an absolute bleeding sub-score of 0 or 1

Source: Listing 16.x.x
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Table 14.2.2.6 Summary of SF-36 Component Summary Measures Scores (Per Protocol Set)

		ABX-464 (N=xx)	Placebo (N=xx)
Mental Health Component Summary Measure			
Baseline	N	xx	xx
	Mean	xx.xx	xx.xx
	SD	xx.xx	xx.xx
	Median	xx.xx	xx.xx
	Minimum	xx.x	xx.x
	Maximum	xx.x	xx.x
Week 4	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		
Change from baseline to Week 4	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		
Week 8	N	xx	xx
	Mean	xx.xx	xx.xx
	Etc		
Change from baseline to Week 8	N	xx	xx
	Mean	xx.xx	xx.xx

Etc

Repeat for physical health component summary measure on a new page

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ABX464-101 ddMMMyyyy

Table 14.3.1.1 Summary of Adverse Events (Safety Set)

	ABX-464 (N=xx)		Placebo (N=xx)		Total (N=xx)		p-value*
	n	N (%)	n	N (%)	n	N (%)	
Any Adverse Event	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	
Any Treatment-Emergent Adverse Event	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	x.xxxx
Any Serious Adverse Event	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	
Any Severe Adverse Event	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	
Adverse Event leading to death	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)	

The table presents number of events (n) and number and percentage of patients (N(%))
The denominator for each percentage is the number of patients within the column

*TEAE rate between treatments is compared using stratified likelihood ratio chi-square test at a one-sided 10% significance level.

Source: Listing 16.x.x
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ABX464-101 ddMMMyyyy

Table 14.3.1.2.1 Summary of Treatment-Emergent Adverse Events: Period 1 (Safety Set)

	ABX-464 (N=xx)		Placebo (N=xx)		Total (N=xx)	
	n	N (%)	n	N (%)	n	N (%)
Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Serious Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Drug-Related Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Serious Drug-Related Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Treatment-Emergent Adverse Events leading to Study Drug Discontinuation	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

The table presents number of events (n) and number and percentage of patients (N(%))
The denominator for each percentage is the number of patients within the column

Source: Listing 16.x.x
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This layout also applies to :
Table 14.3.1.2.2 Summary of Treatment-Emergent Adverse Events: Period 2 (Safety Set)

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Table 14.3.1.3.1.1 Treatment-Emergent Adverse Events, by SOC and PT: Period 1 (Safety Set)

	ABX-464 (N=xx)		Placebo (N=xx)		Total (N=xx)	
	n	N (%)	n	N (%)	n	N (%)
Any Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
SOC	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Etc	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
SOC	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Etc	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

The table presents number of events (n) and number and percentage of patients (N(%))
The denominator for each percentage is the number of patients within the column

Source: Listing 16.x.x
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This layout also applies to:
Table 14.3.1.3.1.2 Treatment-Emergent Adverse Events, by SOC and PT: Period 2 (Safety Set)
Table 14.3.1.3.2.1 Severe Treatment-Emergent Adverse Events, by SOC and PT: Period 1 (Safety Set)
Table 14.3.1.3.2.2 Severe Treatment-Emergent Adverse Events, by SOC and PT: Period 2 (Safety Set)
Table 14.3.1.3.3.1 Serious Treatment-Emergent Adverse Events, by SOC and PT: Period 1 (Safety Set)
Table 14.3.1.3.3.2 Serious Treatment-Emergent Adverse Events, by SOC and PT: Period 2 (Safety Set)
Table 14.3.1.3.4.1 Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 1 (Safety Set)
Table 14.3.1.3.4.2 Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 2 (Safety Set)
Table 14.3.1.3.5.1 Serious Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 1 (Safety Set)
Table 14.3.1.3.5.2 Serious Drug-Related Treatment-Emergent Adverse Events, by SOC and PT: Period 2 (Safety Set)
Table 14.3.1.3.6.1 Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation, by SOC and PT: Period 1 (Safety Set)
Table 14.3.1.3.6.2 Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation, by SOC and PT: Period 2 (Safety Set)

ABX464-101 ddMMMyyyy

Table 14.3.1.3.7.1 Treatment-Emergent Adverse Events, by Intensity and SOC and PT: Period 1 (Safety Set)

	ABX-464 (N=xx)		Placebo (N=xx)		Total (N=xx)	
	n	N (%)	n	N (%)	n	N (%)
Any Mild Treatment-Emergent Adverse Events	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
SOC	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Etc	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
SOC	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
PT	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Etc	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

The table presents number of events (n) and number and percentage of patients (N(%))
The denominator for each percentage is the number of patients within the column

Repeat for moderate and severe intensity on a new page.

Source: Listing 16.x.x
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This layout also applies to:
Table 14.3.1.3.7.2 Treatment-Emergent Adverse Events, by Intensity and SOC and PT: Period 2 (Safety Set)

ABX464-101 ddMMMyyyy

Table 14.3.2.1.1 Summary of Haematology Parameters (Safety Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Haematocrit				
Baseline	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Day 7				
Etc				
Etc				

Source: Listing 16.x.x
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Programming note: start each parameter on a new page

This layout also applies to:

Table 14.3.2.1.2 Summary of Biochemistry Parameters (Safety Set)
Table 14.3.2.1.3 Summary of Stool Results (Safety Set)

ABX464-101 ddMMMyyyy

Table 14.3.5.1 Shift Table of Haematology Parameters (Safety Set)

	ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
	Baseline	Baseline	Baseline
	Normal	Normal	Normal
	Abnormal NCS	Abnormal NCS	Abnormal NCS
	Abnormal CS	Abnormal CS	Abnormal CS
Haematocrit			
Day 7			
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 14			
Etc			
Etc			

CS=Clinically Significant; NCS=Non Clinically Significant
The denominator for each percentage is the number of non-missing observations within the column
Baseline is defined as the last non-missing value before the first dose of study drug.

Source: Listing 16.x.x
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This layout also applies to:
Table 14.3.2.2.2 Shift Table of Biochemistry Parameters (Safety Set)
Table 14.3.2.2.3 Shift Table of Stool Results (Safety Set)
Table 14.3.4.2 Shift Table of 12-Lead Electrocardiogram (Safety Set)

ABX464-101

ddMMMyyyy

Table 14.3.3 Vital Signs, including Weight (Safety Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Systolic BP (mmHg)				
Baseline	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Day 7				
Etc				
Diastolic BP (mmHg)				
Heart Rate (bpm)				
Body temperature (°C)				
Weight (kg)				

Source: Listing 16.x.x
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ABX464-101 ddMMMyyyy

Table 14.3.4.1 12-Lead Electrocardiogram (Safety Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Baseline	N	xx	xx	xx
	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 28				
Etc				

Source: Listing 16.x.x

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ABX464-101 ddMMMyyyy

Table 14.3.5 Study Drug Exposure (Full Analysis Set)

		ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Number of dose intakes	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Median	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
Study drug exposure (days)	N	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	Etc			

Study drug exposure (days) is calculated as (date of last dose) - (date of first dose) + 1

Source: Listing 16.x.x

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ABX464-101 ddMMMyyyy

Table 14.3.6.1 Prior Medications (Full Analysis Set)

	ABX-464 (N=xx)	Placebo (N=xx)	Total (N=xx)
Any prior medication[1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
X, xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XON, xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XONXX, xxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XONXX, xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XON, xxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
XONXX, xxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc			
Etc			

[1] Medication that stopped prior to date of first dose

WHO-DDE version <XX.X>
The denominator for each percentage is the number of patients in the full analysis set within the column

Source: Listing 16.x.x
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This layout also applies to:
Table 14.3.6.2 Concomitant Medications (Full Analysis Set)

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Listing 16.2.1 Discontinued Patients and Reason for Withdrawal

Treatment	Centre/ Patient number	First dose date	Last dose date	Date of withdrawal	Main reason for withdrawal
xxxxxx	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xxxxxxxxxxxxxxxxxxxxxxxxxx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xxxxxxxxxxxxxxxxxxxxxxxxxx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xxxxxxxxxxxxxxxxxxxxxxxxxx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xxxxxxxxxxxxxxxxxxxxxxxxxx

Etc

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ABX464-101 ddMMMyyyy

Listing 16.2.2 Protocol Deviations

Treatment	Centre/ Patient number	Major deviation	Protocol deviation
xxxxxx	xxx-xxxx	Yes/No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxx-xxxx	Yes/No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxx-xxxx	Yes/No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxx-xxxx	Yes/No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
Etc			

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ddMMMyyyy

Listing 16.2.3 Analysis Datasets

Treatment	Centre/ Patient number	Full Analysis Set	Per Protocol Analysis Set	Safety Set
xxxxxx	xxx-xxxx	Yes/No	Yes/No	Yes/No
	xxx-xxxx	Yes/No	Yes/No	Yes/No
	xxx-xxxx	Yes/No	Yes/No	Yes/No
	xxx-xxxx	Yes/No	Yes/No	Yes/No

Etc

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ABX464-101 ddMMMyyyy

Listing 16.2.4 Demographic Data

Treatment	Centre/ Patient number	Date of screening	Date of birth	Age (years)	Gender	Race	Weight (kg)	Height (cm)	BMI (kg/m²)
xxxxxx	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x

Etc

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ABX464-101 ddMMMyyyy

Listing 16.2.5 Study Drug Exposure and Compliance

Treatment	Centre/ Patient number	Date of compliance check	Date of first dose	Date of last dose	Duration of exposure (days)	Capsules used	Capsules expected to be used	Capsules returned	Capsules lost
xxxxxx	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	xx	xx	xx	xx	xx
	Etc								
Etc									

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ABX464-101 ddMMMyyyy

Listing 16.2.6 Efficacy Response Data

Treatment	Centre/ Patient number	Is Total Mayo Score ≤2?	Any individual sub-score >1?	Clinical remission achieved
xxxxxx	xxx-xxxx	Yes/No	Yes/No	Yes/No
	xxx-xxxx	Yes/No	Yes/No	Yes/No
	xxx-xxxx	Yes/No	Yes/No	Yes/No
	xxx-xxxx	Yes/No	Yes/No	Yes/No
Etc				

ABX464-101 ddMMMyyyy

Listing 16.2.7 Adverse Event Listing

Treatment	Centre/ Patient number	Adverse Event Preferred Term SOC Term	Onset date	Resolution date /ongoing	Outcome	Serious	Severity	Relationship to study drug	Action taken with study drug	Other action taken
xxxxxxx	xxx-xxxx	xxxxxxxxx xxxxxxxx xxxxxxx	ddMMMyyyy	ddMMMyyyy/ Ongoing	Resolved/resolved without sequelae /Etc	Yes /No	Grade 1/ Grade 2/ etc	Yes/No	None /Temporary discontinuation /Etc	Concomitant medication (CM no.)/ Procedure (PR No.)
		xxxxxxxxx xxxxxxxx xxxxxxx	ddMMMyyyy	ddMMMyyyy/ Ongoing	Resolved/resolved without sequelae /Etc	Yes /No	Grade 1/ Grade 2/ etc	Yes/No	None /Temporary discontinuation /Etc	Concomitant medication (CM no.)/ Procedure (PR No.)
		Etc								
Etc										

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ABX464-101 ddMMMyyyy

Listing 16.2.8.1 Laboratory Measurements: Haematology

Parameter	Treatment	Centre/ Patient number	Visit	Was sample taken?	Result	Unit	Investigator's interpretation
Haemoglobin	xxxxxxx	xxx-xxxx	Screening	Yes/ No (reason)	xxx.xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
			Day 0	Yes/ No (reason)	xxx.xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
			Day 7*	Yes/ No (reason)	xxx.xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
			Etc		xxx.xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
		xxx-xxxx	Screening		xxx.xx	xxxx	Normal/ Abnormal CS/ Abnormal NCS
			Etc				
		Etc					
	Etc						

Etc

*Outside the visit window

CS=Clinically Significant; NCS=Non Clinically Significant

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This layout also applies to:

Listing 16.2.8.2 Laboratory Measurements: Biochemistry

Listing 16.2.8.3 Laboratory Measurements: Stool Results

ABX464-101 ddMMMyyyy

Listing 16.4.1 Final Status

Treatment	Centre/ Patient number	First dose date	Last dose date	Completed treatment	Primary reason for discontinuation (specify)	Was the randomisation code broken? (date and reason)	Will subject enter follow-up?
xxxxxx	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	Yes/No	xxxxxxxxxx (specify)	Yes (ddMMMyyy; xxxxxx)/ No	Yes/No
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	Yes/No	xxxxxxxxxx (specify)	Yes (ddMMMyyy; xxxxxx)/ No	Yes/No
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	Yes/No	xxxxxxxxxx (specify)	Yes (ddMMMyyy; xxxxxx)/ No	Yes/No
	xxx-xxxx	ddMMMyyyy	ddMMMyyyy	Yes/No	xxxxxxxxxx (specify)	Yes (ddMMMyyy; xxxxxx)/ No	Yes/No

Etc

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ddMMMyyyy

Listing 16.4.2 Patient Visit Dates

Treatment	Centre/ Patient number	Visit	Date
xxxxxx	xxx-xxxx	xx	ddMMMyyyy
		xx	ddMMMyyyy
		xx*	ddMMMyyyy
		xx	ddMMMyyyy

Etc

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ABX464-101 ddMMMyyyy

Listing 16.4.3.1 Inclusion Criteria

Protocol versions: XXXX

Definition of criterion	
1	xxx
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	

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Note: The list of criteria will be presented on the first page of the listing. Patient data will start on page 2.

Programming note: Repeat for each protocol amendment if the criteria change

ABX464-101 ddMMMyyyy

Listing 16.4.3.1 Inclusion Criteria

Treatment	Centre / Patient number	Protocol version	Criteria 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
xxxxxx	xxx-xxxx	x.xx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
	xxx-xxxx	x.xx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
	xxx-xxxx	x.xx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
	xxx-xxxx	x.xx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Etc

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This layout also applies to:

Listing 16.4.3.2 Exclusion Criteria

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ddMMMyyyy

Listing 16.4.4 Medical History

Treatment	Centre/ Patient number	Date of UC Diagnosis	Any other conditions?	Condition SOC PT	Date of diagnosis	Ongoing/ End date
xxxxxx	xxx-xxxx	ddMMMyyyy	Yes/No	xxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxx	ddMMMyyyy	Yes/ No (ddMMMyyyy)
		ddMMMyyyy	Yes/No	xxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxx	ddMMMyyyy	Yes/ No (ddMMMyyyy)
Etc						

ABX464-101 ddMMMyyyy

Listing 16.4.5.1 Raw Efficacy Scores: Mayo Score

Treatment	Centre/ Patient number	Visit	MCS Symptomatic Sub-score Criteria / Site assessment		MCS Endoscopy Sub-score Criteria / Site Assessment		MCS Endoscopy Sub-score Criteria / Central Reader Assessment		Overall MCS Endoscopic Sub-Score
			Question	Result	Question	Result	Question	Result	
xxxxxx	xxx-xxxx	Baseline	Stool frequency	Normal / 1 to 2 stools per day more than normal/ etc	Was assessment done?	Yes (area; result)/ No/ NA	Was assessment done?	Yes (area; result)/ No/ NA	xx
			Rectal bleeding	No blood seen /					
			Physician's Global Assessment	Normal = 0					
			Etc	Etc					
		Etc*							
Etc									

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ddMMMyyyy

Listing 16.4.5.2.1 Raw Efficacy Data: SF-36 Questionnaire

Treatment	Centre/ Patient number	Question	Baseline	Week 4	Week 8
xxxxxx	xxx-xxxx	Was SF-36 performed?	Yes/No	Yes/No	Yes/No
		Date	ddMMMyyyy	ddMMMyyyy*	ddMMMyyyy
		1	Excellent/ Very good/ Good/ Fair /Poor	Excellent/ Very good/ Good/ Fair /Poor	Excellent/ Very good/ Good/ Fair /Poor
		2	Much better/ Somewhat better/ About the same/ Somewhat worse/ Much worse	Much better/ Somewhat better/ About the same/ Somewhat worse/ Much worse	Much better/ Somewhat better/ About the same/ Somewhat worse/ Much worse
		3	Yes, a lot / Yes, a little/ No	Yes, a lot / Yes, a little/ No	Yes, a lot / Yes, a little/ No
		4	Yes, a lot / Yes, a little/ No	Yes, a lot / Yes, a little/ No	Yes, a lot / Yes, a little/ No
Etc		Etc			

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Listing 16.4.5.2.2 Raw Efficacy Data: SF-36 Component Summary Measures and Domain Scales

Treatment	Centre/ Patient number	Type	Name	Baseline	Week 4	Week 8
xxxxxx	xxx-xxxx	Component Summary Measure	Mental Health	xx	xx	xx
			Physical Health	xx	xx	xx
		Domain Scale	Physical Functioning	xx	xx	xx
			Role-Physical	xx	xx	xx
			Bodily Pain	xx	xx	xx
			General Health	xx	xx	xx
			Vitality	xx	xx	xx
			Social Functioning	xx	xx	xx
			Role-Emotional	xx	xx	xx
			Mental Health	xx	xx	xx
			Reported Health Transition	xx	xx	xx
Etc		Etc				

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ddMMMyyyy

Listing 16.4.6 Study Drug Administration

Centre/ Subject number	Treatment	Study Treatment Day	Intake Date	Intake Time	Number of capsules taken	Dose of each capsule (mg)	Comments
xx/xx-xx	xxxxxx	xxxxx	ddMMMyyyy	hhmm	xx	xx	xxxxxxxx
		xxxxx	ddMMMyyyy	hhmm	xx	xx	xxxxxxxx
		xxxxx	ddMMMyyyy	hhmm	xx	xx	xxxxxxxx
Etc							

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ddMMMyyyy

Listing 16.4.7 Vital Signs

Treatment	Centre/ Patient number	Visit	Date of visit	Systolic BP (mmHg)	Diastolic BP (mmHg)	Heart rate (beats/min)	Body temperature (°C)	Weight (kg)
xxxxxx	xxx-xxxx	xx	ddMMMyyyy	xxx	xxx	xxx	xx.x	xx.x
		xx	ddMMMyyyy	xxx	xxx	xxx	xx.x	xx.x
		xx*	ddMMMyyyy	xxx	xxx	xxx	xx.x	xx.x
		xx	ddMMMyyyy	xxx	xxx	xxx	xx.x	xx.x

Etc

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ABX464-101 ddMMMyyyy

Listing 16.4.8 Physical Examination

Treatment	Centre/ Patient number	Visit	Date of Visit	Body system	Status	Abnormality
xxxxxx	xxx-xxxx	Screening	ddMMMyyyy	Eyes	Normal/ Abnormal NCS/ Abnormal CS/ Not done	xxxxxxxxxxxxxxxxxxxxxxxxx
				Ear/Nose/Throat	Normal/ Abnormal NCS/ Abnormal CS/ Not done	xxxxxxxxxxxxxxxxxxxxxxxxx
				Lungs/Thorax	Normal/ Abnormal NCS/ Abnormal CS/ Not done	xxxxxxxxxxxxxxxxxxxxxxxxx
				Etc		
		xx*	ddMMMyyyy	Eyes	Normal/ Abnormal NCS/ Abnormal CS/ Not done	xxxxxxxxxxxxxxxxxxxxxxxxx
				Etc		
Etc						

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Listing 16.4.9 12-Lead Electrocardiogram

Treatment	Centre/ Patient number	Visit	Date of visit	Time	Investigator's interpretation	Abnormality
xxxxxx	xxx-xxxx	Day 0	ddMMMyyyy	hh:mm	Normal/ Abnormal NCS/ Abnormal CS	xxxxxxxxxx
		Day 28*	ddMMMyyyy	hh:mm	Normal/ Abnormal NCS/ Abnormal CS	xxxxxxxxxx
		Etc				
	Etc					
Etc						

*Outside the visit window

ABX464-101 ddMMMyyyy

Listing 16.4.10 Prior Medications

Treatment	Centre/ Patient number	Therapy ATC Code PT	Indication	Total Daily Dose	Unit	Frequency	Route	Start date (Stop date)	Given for Procedure/ Non-Drug Therapy? (Related procedure number)
xxxxxx	xxx-xxxx	xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	xxxxxxx	xx.x	xxx	xxx	xxx	ddMMMyyyy (ddMMMyyyy)	Yes (xxx) / No
		xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	xxxxxxx	xx.x	xxx	xxx	xxx	ddMMMyyyy (ddMMMyyyy)	Yes (xxx) / No
		xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	xxxxxxx	xx.x	xxx	xxx	xxx	ddMMMyyyy (ddMMMyyyy)	Yes (xxx) / No
Etc									

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This layout also applies to:

Listing 16.4.11 Concomitant Medications (Programming note: can have stop date as 'ongoing')

ABX464-101 ddMMMyyyy

Listing 16.4.12 Procedures/ Non-Drug Therapies

Treatment	Centre/ Patient number	Procedure /Therapy	Start date	Ongoing / End date	Given for pre-existing condition? (Related medical history number)	Given for adverse event? (Related adverse event number)
xxxxxx	xxx-xxxx	xxxxxxxxxxxxxx	ddMMMyyyy	Yes / No (ddMMMyyyy)	Yes (xxx) / No	Yes (xxx) / No
		xxxxxxxxxxxxxx	ddMMMyyyy	Yes / No (ddMMMyyyy)	Yes (xxx) / No	Yes (xxx) / No
		xxxxxxxxxxxxxx	ddMMMyyyy	Yes / No (ddMMMyyyy)	Yes (xxx) / No	Yes (xxx) / No
Etc						

ABX464-101 ddMMMyyyy

Listing 16.4.13 Pregnancy Test

Treatment	Centre/ Patient number	Visit	Test done	Reason not done	Date of test	Result
xxxxxx	xxx-xxxx	Screening	Yes/No/Not applicable	xxxxxxxxxxxx	ddMMMyyyy	Positive/Negative
		xx	Yes/No/Not applicable	xxxxxxxxxxxx	ddMMMyyyy	Positive/Negative
		xx*	Yes/No/Not applicable	xxxxxxxxxxxx	ddMMMyyyy	Positive/Negative
		xx	Yes/No/Not applicable	xxxxxxxxxxxx	ddMMMyyyy	Positive/Negative
		Etc				
Etc						

*Outside the visit window

ABX464-101 ddMMMyyyy

Listing 16.4.14 Laboratory and Other Assessment Samples Collection

Parameter	Treatment	Centre/ Patient number	Visit	Sample taken	Reason not done	Date of test	Result	Interpretation
xxxxxx	xxxxxx	xxx-xxxx	Screening	Yes/No	xxxxxxxxxxxx	ddMMMyyyy	xx	Normal/ Abnormal CS/ Abnormal NCS
			xx	Yes/No	xxxxxxxxxxxx	ddMMMyyyy	xx	Normal/ Abnormal CS/ Abnormal NCS
			xx*	Yes/No	xxxxxxxxxxxx	ddMMMyyyy	xx	Normal/ Abnormal CS/ Abnormal NCS
			xx	Yes/No	xxxxxxxxxxxx	ddMMMyyyy	xx	
			Etc					
	Etc							

*Outside the visit window

Programming note: Parameters may include ESR, thyroid function surveillance, faecal calprotectin, miRNA (Paxgene), miRNA (RNA later), two rectal biopsies, optional two sigmoidal biopsies

Result and interpretation columns should be blank for all parameters except ESR and thyroid function surveillance (result should be blank for this too)

16 APPENDICES

16.1 STUDY FLOW CHART

			Study Treatment Period							
	D-14	Randomization~~D-7~~	D0	D7	D14	D21	D28	D42	D56	D63-EOS
Time Window	± 3 days	~~± 3 days~~		± 2 days	± 2 days	± 2 days	± 2 days	± 4 days	± 4 days	± 2 days
Obtained Inform Consent	X									
Check of IN/EX Criteria	X	X								
Physical Examination	X		X	X	X	X	X	X	X	X
Body Weight (kg)	X		X	X	X	X	X	X	X	X
Height Measurement (cm)	X									
Medical History and Concomitant Medications	X									
Vital signs	X		X	X	X	X	X	X	X	X
ECG (12 lead)	X		X				X		X	X
Randomization		X								
Blood Pregnancy test (WOCBP)	X		X				X		X	
Hematology + Biochemistry	X		X	X	X		X		X	X
Mayo score (Total or Partial)	X		X	X	X	X	X	X	X	X
Faecal calprotectin ~~(optional)~~			X				X		X	X
Rectal microbiota	X								X	
Sigmoidoscopy	X								X	
SF-36 (Questionnaire)			X				X		X	
ABX464/placebo treatment dispensation and subject diary review			X				X			
Blood samples drug pK			X*				X*			
Samples for miRNA (Paxgene tubes/RNA Later)			X				X		X	
Adverse Events recording			X	X	X	X	X	X	X	X

* Applicable to the first 9 subjects randomized / PK predose, 0.5, 1, 1.5, 2, 2.5, 3, 4, 8 and 12 post-dose