Statistical Analysis Plan

ABX464-102

A follow-up Phase IIa study to evaluate the long-term safety and efficacy profile of ABX464 given at 50 mg once daily in subjects with Moderate to Severe Active Ulcerative Colitis.

Prepared for:

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CONFIDENTIAL

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Author:

Version: Final 1.0

The undersigned have reviewed and revised this SAP and find it to be consistent with the study requirements:

_____ _____

, Statistician, Simbec-Orion Group Ltd. Date

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, Head of Statistics, Simbec-Orion Group Ltd. Date

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GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
AESI	Adverse Event of Special Interest
ALT	Alanine Transaminase
AST	Aspartate Transaminase
ATC	Anatomical Therapeutic Chemical
BLQ	Below the Limit of Quantification
BMI	Body Mass Index
BUN	Blood Urea Nitrogen
CI	Confidence Interval
CPK	Creatine Phosphokinase
CRA	Clinical Research Associate
CRF	Case Report Form
CRP	C-Reactive Protein
CS	Clinically Significant
CSR	Clinical Study Report
D	Day
DBL	Database Lock
DRM	Data Review Meeting
DSMB	Data Safety Monitoring Board
E	Number of Events in the Sample
ECG	Electrocardiogram
EoS	End of Study
ESR	Erythrocyte Sedimentation Rate
gGT	gamma-Glutamyl Transferase
GLDH	Glutamate Dehydrogenase
GLS	Global Longitudinal Strain
ICH	International Conference on Harmonisation
ICVSC	Independent Cardiovascular Safety Committee

ITT	Intent-to-Treat Population
LDH	Lactate Dehydrogenase
LLQ	Lower Limit of Quantification
LOCF	Last Observation Carried Forward
LS Mean	Least Squares Mean
LVEF	Left Ventricle Ejection Fraction
M	Month
MMS	Modified Mayo Score
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
miR	micro-RNA
N	Number of Patients in the Population
n	Number of Patients in the Sample
NCS	Not clinically significant
NRI	Non-responder Imputation
NT-ProBNP	N-terminal pro-brain natriuretic peptide
OC	Observed Cases
o.d	Once daily
pMMS	Partial Modified Mayo Score
pMS	Partial Mayo Score
PT	Preferred Term
TMS	Total Mayo Score
QC	Quality Control
QoL	Quality of Life
RV	Right Ventricle
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SE	Standard Error
SEM	Standard Error of the Mean
SF-36	Quality of Life Questionnaire

SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
UC	Ulcerative Colitis
WBC	White Blood Cell
WHO-DDE	World Health Organisation Drug Dictionary Enhanced

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 ABX464-102 and should be read in conjunction with the study protocol and case report form (CRF).

This version of the plan has been developed using the protocol Version 7.0 dated 07FEB2022 and CRF specifications dated 11JAN2022. Any further changes to the protocol or CRF will be reviewed for potential impact on the SAP which will be amended if it is deemed necessary.

At the time of writing this version of the SAP, recruitment is terminated, treatment is ongoing.

Draft 1 was reviewed by the Simbec-Orion project manager, medical writer and statistical reviewer. The analysis plan will be finalised and approved by the sponsor prior to unblinding of study treatment codes for the planned interim analysis and prior to database lock.

1.2 CHANGES FROM PROTOCOL

- The echocardiography secondary endpoints will be included in a separate report.
- Sustained clinical remission and sustained endoscopic remission/improvement will be summarized as part of the secondary endpoints.
- Observed Cases (OC) Set and Non-responder Imputation (NRI) Set are defined for populations instead of the populations defined in the protocol.
- In the definition of corticosteroid-free clinical remission (Section 11.3.1.6), time interval is changed from 12 weeks to 90 days for consistency with other Abivax studies.
- In the definition of clinical response (Section 11.3.1.6), Modified Mayo Score is used instead of Total Mayo Score for consistency with other Abivax studies.
- All efficacy variables will be summarized based on the following subgroups:
    - Patients being in clinical response at BOLS and not being in clinical response at BOLS
    - Patients previously treated with biological drugs and naive from biological drugs.
- In the Synopsis and Section 2.4 of the protocol, M24 is missing from the list of timepoints for clinical remission, clinical response, endoscopic improvement, endoscopic remission and corticosteroid-free clinical remission inconsistently with further sections. This timepoint is included in the current SAP to ensure that these secondary endpoints are analysed for all required timepoints.

1.3 CHANGES FROM PREVIOUS VERSIONS OF THE SAP

No previous versions of the SAP exist.

2 STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVE

The primary objective of the study is to evaluate the long-term safety of ABX464 given at 50 mg once daily in subjects with Moderate to Severe Active Ulcerative Colitis.

2.2 SECONDARY OBJECTIVES

The secondary objectives are:

- To evaluate the long-term effect of ABX464 on clinical and endoscopic remission in subjects with Moderate to Severe Active Ulcerative Colitis assessed by the Mayo Score (MS);
- To evaluate the long-term effect of ABX464 on inflammatory markers (C-Reactive Protein (CRP), Calprotectin and Erythrocyte Sedimentation Rate (ESR));
- To evaluate the long-term of ABX464 on Quality of Life (QoL) measured by the Quality of Life Questionnaire (SF-36) questionnaire in subjects with Moderate to Severe Active Ulcerative Colitis until M24.

The echocardiography objective is to evaluate the effect of ABX464 on cardiac function as assessed through echocardiograms and will be included in a separate report.

3 STUDY DESIGN

3.1 OVERVIEW

This study is an open-label study aiming at evaluating the long-term safety and the efficacy profile of ABX464 given once a day (o.d) at 50 mg in subjects who have been previously enrolled in the ABX464-101 clinical study (induction study) and who are willing to continue their treatment.

All subjects receive ABX464 given at 50 mg o.d irrespective of their previous treatment received in the ABX464-101 study (i.e. ABX464 or Placebo). With respect to this, there will be 2 groups: 50mg ABX464 (101 study) + 50mg ABX464 (102 extension) and Placebo (101 study) + 50mg ABX464 (102 extension).

The actual treatment received by a subject throughout the previous study (ABX464-101) was not known at the time the subjects entered this follow-up study.

The enrolment in this follow-up study was based on the willingness of the subject to carry on his/her participation and also based on investigator's judgement.

Subjects are treated with ABX464 for an overall period of 48 months. Subjects are followed up weekly during the first month, every two weeks during the second month and then on a monthly basis until M24, then quarterly from M24 to M48.

At M48, depending on their clinical response, eligible patients willing to continue study treatment will be offered to take part into a long term follow up safety study (ABX464-108 study). ABX464-108 study is

a separate study requiring health authorities and ethics committees' approval. If patients are not eligible to pursue treatment in this long-term follow-up study, they will be followed for 4 additional weeks for safety purposes before End of study Visit.

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). Patients must have completed the initial 2-month treatment phase (ABX464-101 study). Details of the inclusion and exclusion criteria are presented in the protocol and amendments.

3.3 Study Treatment

All subjects receive ABX464 50 mg o.d irrespective of their previous treatment received in the ABX464-101 study (i.e. ABX464 or Placebo). With respect to this, there will be 2 groups:

	ABX464-101 treatment	ABX464-102 treatment (extension study)
Group #1	50mg ABX464	50mg ABX464
Group #2	Placebo	50mg ABX464

3.4 Study Timepoints

Subjects were enrolled in the present study at Day (D) 0 and are treated for an overall duration of 48 months.

From ABX464 treatment stop onwards, subjects will be followed-up for 4 additional weeks.

Visit	Visit	Window
1	Screening/ D0	
2	D7	± 2 days
3	D14	± 2 days
4	D21	± 2 days
5	D28	± 4 days
6	D42	± 2 days
7	D56/ M2	± 4 days
8	Mx+1 to M24	± 4 days
9	M27 to M48*	± 14 days
EoS	EoS**	± 4 days

*: Visits are performed quarterly after M24 (at M27, M30, M33, M36, M39, M42, and M48)
**: End of Study visit: 28 days after ABX464 Stop

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 Schedule.

3.5 Sample Size Considerations

Not applicable. All patients in this study are those who were included in the ABX464-101 study.

3.6 Randomisation

Not applicable. All the patients will receive ABX464 50mg o.d.

4 STUDY VARIABLES

4.1 Primary Variable

The primary endpoint of this study is defined as the number of incidences of treatment-emergent adverse events in the ABX464 treated subjects.

4.2 Secondary Variables

The secondary endpoints of this study are:

- The change from Day 0 in Total Mayo Score.
- The change from Day 0 in Partial Mayo Score.
- The time to Ulcerative Colitis (UC) worsening.
- The change from Day 0 in faecal calprotectin, CRP levels and ESR.
- The scores and changes from Day 0 in SF-36 Questionnaire scores.
- The micro-RNA (miR-124) expression at month 12, month 36 and month 48.
- The number of incidences of treatment-emergent serious adverse events.
- The number of incidences of treatment-emergent adverse events of special interest.
- The number of incidences of adverse events leading to investigational product discontinuation.
- The number of incidences of specific laboratory abnormalities.
- Clinical remission
- Corticosteroid-free clinical remission
- Clinical response
- Endoscopic improvement
- Endoscopic remission
- Sustained clinical remission and sustained endoscopic remission/improvement

The echocardiography secondary endpoints will be included in a separate report.

4.3 Pharmacokinetic Variables

Pharmacokinetic variables are not evaluated in this study.

4.4 Pharmacodynamic Variables

Pharmacodynamic variables are not evaluated in this study.

4.5 Other Outcome Variables

Not applicable.

4.6 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
- Electrocardiogram (ECG)

5 DEFINITIONS

5.1 DEFINITIONS

Study Drug: Study drug is taken to mean ABX464 50 mg o.d.

Baseline: Baseline is defined by patient and by variable as the last non-missing (including repeat or unscheduled) value before the first dose of study drug. 2 baselines will be defined:

- Baseline Induction Study (BIS): Day 0 of ABX464-101 study
- Baseline Open-Label Study (BOLS): Day 56 of ABX464-101 study

BIS is defined as a baseline for ABX464-101 (induction) study and BOLS is defined as a baseline for ABX464-102 (open-label) study.
Primarily, baseline without the study number refers to baseline of the current study (BOLS).

Study Day: Study day is the number of days since start of treatment for ABX464-102 study where the date of first dose is counted as 1.

Treatment Exposure: 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

Compliance: Compliance is the number of doses actually taken divided by the scheduled number of doses expressed as a percentage during the extension period or until early withdrawal.

Non-compliance: Non-compliance is defined as taking less than 80% or more than 120% of study medication during the extension period or until early withdrawal.

6 ANALYSIS POPULATION

Membership of the analysis populations will be reviewed and agreed at a Data Review Meeting (DRM) before database lock.

6.1 OBSERVED CASES (OC) SET

The Observed Cases (OC) Set is defined as those subjects included in the study, who have received at least one dose of the study treatment. This set will use all data available at timepoints without any imputations for missing dichotomous values, and with Last Observation Carried Forward (LOCF) imputation (described in section 10.4) for missing continuous values.

The OC Set will be used for all safety and efficacy analyses.

6.2 NON-RESPONDER IMPUTATION (NRI) SET

The Non-responder Imputation (NRI) Set will consist of all patients in the OC Set with the following rules applied to the missing values:

- for dichotomous values, patient will be considered as non-responder
- for continuous values, LOCF imputation will be applied as described in section 10.4.

Efficacy analyses will be repeated for the NRI Set.

7 SAFETY MONITORING

An independent Data Safety Monitoring Board (DSMB), with expertise and experience in the pathology, and without direct involvement in the conduct of the trial, is set up specifically to guarantee effective protection of subjects, ensure the ethical conduct of the trial, benefit/risk ratio of the trial, and to ensure the independent review of the scientific results during the trial and at the end of the trial.

The DSMB meetings were held on a monthly basis until December 2019 and then quarterly from January 2020 onwards. The DSMB may recommend the early termination of the trial at any time.

In addition, DSMB reviews all potential causally related Serious Adverse Events within 7 days of the initial report.

The DSMB has only a consultative role; it will inform the sponsor who will decide whether the DSMB recommendation will be followed. A DSMB charter must be available upon submission of the trial (initial protocol) to the relevant competent authorities.

An Independent Cardiovascular Safety Committee (ICVSC), comprised of 3 cardiologists with experience from drug development, will be formed as detailed in the Charter. The ICVSC will be responsible for an on-going evaluation of cardiac adverse events of special interest (Cardiac AESIs), for treatment emergent echocardiographic findings, and for treatment emergent changes of cardiac safety biomarkers (as detailed above). The ICVSC will review cardiac adverse events on an on-going basis, meet regularly and provide recommendations to Sponsor and DSMB regarding study procedures and conduct.

8 INTERIM ANALYSES

An interim analysis was performed at M12 outside of Simbec-Orion.

The study analysis will be performed after database lock occurring following the completion of the last subject or its early discontinuation.

9 DATA

9.1 eCRF Data

CRF data will be provided by Simbec-Orion data management to the statistics department as Statistical Analysis System (SAS) datasets in Simbec-Orion standard format which will be used for programming the outputs to be included in the Clinical Study Report (CSR). Populated datasets will be available when programming starts. These may contain dummy data if real data are not yet available.

9.2 External Data

9.2.1 Laboratory Data

For hematology and biochemistry local laboratory are used. All lab dosages are done locally.

The following clinical laboratory parameters are measured:

Hematology: Hemoglobin, Hematocrit, White Blood Cell (WBC), Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelet count, ESR, Fibrinogen, Prothrombin time and/or INR.

Biochemistry: Sodium, Potassium, Chloride, Calcium, Phosphate, Glucose, Blood Urea Nitrogen (BUN) or urea, Creatinine, Aspartate Transaminase (AST), Alanine Transaminase (ALT), Glutamate Dehydrogenase (GLDH), Lipase, Alkaline phosphatase, gamma-Glutamyl Transferase (gGT), Total bilirubin, Total protein, Albumin, Lactate Dehydrogenase (LDH), C-reactive protein (CRP), Creatine Phosphokinase (CPK), High-sensitive Troponin T and/or I, N-terminal pro-brain natriuretic peptide (NT-proBNP), Amylase.

Stools: Faecal calprotectin.

9.3 Other non-CRF data

Local Laboratory Reference ranges will be provided by the laboratory before site initiation and the required parameters will be transcribed onto the Data Management Laboratory Reference Range Form by the CRA. The CRA will provide reference ranges to the DM, who will use them to verify data on CRF.

9.4 Randomisation list

Not applicable for this study.

9.5 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 are reviewed, but not fully QCd. Outputs may be reviewed by ABIVAX before Database Lock (DBL).

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

10 STATISTICAL METHODS

10.1 General Principles

All variables will be presented descriptively.

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 (50mg ABX464 (101 study) + 50mg ABX464 (102 extension) and Placebo (101 study) + 50mg ABX464 (102 extension)). A total column showing all patients will be included for baseline, safety and efficacy 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 safety tables of continuous variables, standard descriptive statistics (Sample number n, mean, Standard Deviation (SD), Standard Error of the Mean (SEM), median, minimum and maximum) will be presented. In summary tables of continuous variables, standard descriptive statistics (n, mean, 95% confidence interval [CI], SD, median, minimum and maximum and quartiles) will be presented. The minimum and maximum statistics will be presented in summary tables to the same number of significant figures as the original data. The mean, median, SD and SEM will be presented to one more significant than the original data.

- For numeric data which includes non-numeric values (e.g. lab results reported as < 10 or >100) the following principles will be applied when summarising the data:
- Below Limit of Quantification (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 SD and CI 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 Treatment Emergent Adverse Event (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, patient number and visit. 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 ® Enterprise Guide V 8.3 or higher.

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 Stratification and Covariate Adjustment

No stratification or covariate adjustment will be used in this study.

10.3 Interactions

No interactions to be performed.

10.4 Missing Data

For missing continuous variables, Last Observation Carried Forward (LOCF) imputation method will be used for both the OC Set and the NRI Set. Missing dichotomous variables will not be imputed in the OC Set but will be imputed in the NRI Set as non-responder.

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

10.5 Pooling of Sites

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

10.6 Multiple Comparisons

Not applicable.

10.7 Subgroup Analyses

The efficacy variables will be presented according to the following subgroups:

- Patients being in clinical response at BOLS
- Patients not being in clinical response at BOLS
- Patients previously treated with biological drugs
- Patients naive from biological drugs

10.8 Statistical Issues

Not applicable.

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.

11.1 Patient Disposition

The patient disposition table (*Table 14.1.1*) will summarise the following data for all enrolled patients:

- The number (%) of patients in the OC Set
- The number (%) of patients in the NRI Set

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

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

11.2 PATIENT CHARACTERISTICS AT BASELINE

11.2.1 Demographic and Baseline Characteristics

Demographics and other baseline characteristics will be summarized by treatment group (*Table 14.1.3*). This analysis will be conducted on the OC Set.

Age will be calculated using Year of Birth and Date of first treatment 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, childbearing potential, race, height, weight and BMI will be summarised using the OC Set.

In addition to demographic and baseline characteristics, disease characteristics (at Day 0) including Total and Modified Mayo score (TMS and MMS), faecal calprotectin, percentage of subjects with concomitant Corticosteroid, clinical remission, corticosteroid-free clinical remission, clinical response, endoscopic remission, endoscopic improvement will also be summarized using the OC Set.

Clinical remission, corticosteroid-free clinical remission, clinical response, endoscopic remission and endoscopic improvement are defined in Section 11.3.1.6 and 11.3.1.7.

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. Past medical/surgical history and current medical conditions will be summarised by system organ class (SOC) and preferred term (PT). The number (%) of patients reporting each condition will be presented using the OC Set (*Table 14.1.4.1 and 14.1.4.2*).

All medical history will be listed.

11.2.3 Procedures/ Non-Drug Therapies

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

11.3 EFFICACY ANALYSES

All efficacy analysis will be conducted on both OC Set and NRI Set except if otherwise specified and will be summarized based on the following subgroups:

- Patients being in clinical response at BOLS and not being in clinical response at BOLS
- Patients previously treated with biological drugs and naive from biological drugs.

Descriptive statistics will be presented by treatment group and include:

- Quantitative variables: n, mean, SD, minimum and maximum, 95% CI, median and quartiles will be presented when considered relevant. Number of missing values will also be presented.
- Qualitative variables: count and percentage. Number of missing values will also be presented.

Listings showing patients efficacy derivations for Mayo Scores, time to UC worsening and SF-36 Questionnaire will be produced for the efficacy endpoints. All efficacy data will be listed.

If a scheduled endoscopic assessment is not performed, then results from the closest unscheduled assessment within 1 month should be used if available.

11.3.1 Efficacy Variables

Descriptive statistics will be presented for all efficacy variables for each measurement timepoints. All efficacy data will be listed.

11.3.1.1 Mayo Score

The **Total Mayo score** (TMS) consists of 4 items: stool frequency, rectal bleeding, flexible sigmoidoscopic examination, and a physician global assessment of disease activity (see protocol Appendix 3).

A non-invasive 9-point Mayo or **partial Mayo Score** (pMS) incorporates stool frequency, rectal bleeding, and the physician's global assessment of disease activity. The partial Mayo Score has been found to correlate closely with the full Mayo score and to independently have strong discriminative and construct validity and responsiveness to change in disease activity. Either the Partial or the Total Mayo score will be completed at each subject visit by the Investigator.

Modified Mayo Score (MMS) consists of 3 items: stool frequency, rectal bleeding, flexible sigmoidoscopic examination.

Partial Modified Mayo Score (pMMS) consists of only 2 items: stool frequency and rectal bleeding. MMS or pMMS will also be used in descriptive analysis and for efficacy evaluation.

Absolute values and change from BIS and from BOLS to each post BOLS timepoint will be presented using descriptive statistics for Total Mayo Score (TMS), Partial Mayo Score (pMS), Modified Mayo Score (MMS) and partial Modified Mayo Score (pMMS) (*Table 14.2.1.1 and 14.2.1.2*) and for the different components of the Total Mayo Score (stool frequency, rectal bleeding, physician rating of disease activity and mucosal appearance at endoscopy – central reading) (*Table 14.2.1.3 and 14.2.1.4*).

11.3.1.2 Time to UC worsening

Worsening of the UC is defined as a 2-point increase from the screening TMS with 3 days of continuous rectal bleeding confirmed by flexible sigmoidoscopy with an endoscopy sub-score of 2 points or higher.

Descriptive statistics will be presented for the time to UC worsening (*Table 14.2.2.1 and 14.2.2.2*). Time will be calculated in two different ways: from BIS and from BOLS.

11.3.1.3 Faecal calprotectin, CRP levels and ESR

Absolute values and change from BIS and from BOLS to each post BOLS timepoint will be presented using descriptive statistics for faecal calprotectin, CRP and ESR levels (*Table 14.2.3.1 and 14.2.3.2*).

11.3.1.4 SF-36 Questionnaire

Absolute values and change from BIS and from BOLS to each post BOLS timepoint for total score will be presented using descriptive statistics for SF-36 Questionnaire scores (*Table 14.2.4.1 and 14.2.4.2*). SF-36 Questionnaire is assessed at the following visits: D28, D56/M2, and M3 to M24 on a monthly basis.

11.3.1.5 miR-124

Quantification of miR-124 expression in total blood will be measured at Month 12, Month 36 and Month 48 and will not be analysed by Simbec-Orion. It will be detailed in a separate report.

11.3.1.6 Clinical remission, corticosteroid-free clinical remission and clinical response

Clinical remission is achieved when all the following criteria are met in the components of the Mayo Score:

- rectal bleeding sub-score = 0
- central or local endoscopy sub-score <= 1
- stool frequency sub-score <= 1.

Corticosteroid-free clinical remission is defined as clinical remission and concomitant corticosteroid free for ≥ 90 days prior to these timepoints among patients with clinical remission after 8 weeks of induction treatment (at baseline of ABX464-102 study).

Clinical response is defined as:

- reduction in Modified Mayo Score of at least 2 points and >= 30 percent from BIS
- with an accompanying decrease in rectal bleeding sub-score of >= 1 point or absolute rectal bleeding sub-score of <= 1 point.

Proportion of patients (n and percentage) will be presented for patients achieving clinical remission, corticosteroid-free clinical remission and clinical response at M12, M24, M36 and M48 (*Table 14.2.5.1 and 14.2.5.2*).

In addition, shift tables will be presented showing changes from BIS to each post baseline visit and from BOLS to each post baseline visit (*Table 14.2.5.3 and 14.2.5.4*) for clinical remission.

11.3.1.7 Endoscopic improvement and endoscopic remission

Endoscopic improvement is achieved if the Mayo central endoscopic sub-score is 0 or 1.

Endoscopic remission is defined as Mayo central endoscopic sub-score = 0.

Endoscopic improvement and remission (central reading sub-score) will be presented as proportion of patients (n and percentage) (*Table 14.2.6.1 and 14.2.6.2*).

11.3.1.8 Sustained clinical remission and sustained endoscopic remission/improvement

Sustained clinical remission is defined as clinical remission at the given timepoint (M12, M24, M36 or M48) with clinical remission at BOLS.

Sustained endoscopic improvement is defined as endoscopic improvement at the given timepoint (M12, M24, M36 or M48) with endoscopic improvement at BOLS.

Sustained endoscopic remission is defined as endoscopic remission at the given timepoint (M12, M24, M36 or M48) with endoscopic remission at BOLS.

Sustained clinical remission and sustained endoscopic improvement/remission will be presented as proportion of patients (n and percentage) (*Table 14.2.7.1 and 14.2.7.2*).

11.4 PK Analyses

Not applicable.

11.5 PD analyses

Not applicable.

11.6 Safety Analyses

Analysis of safety will be performed on the safety dataset consisting in all patients who received at least one dose of ABX464 in the study. In safety tables of continuous variables, standard descriptive statistics (n, mean, SD, SEM, median, minimum and maximum) will be presented.

11.6.1 Adverse Events

All adverse events (AE) will be classified using the latest version of the MedDRA coding dictionary down to the lower level term.

Events will be classified as treatment-emergent if they started or increased in severity on or after the first date of medication dosing 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.

Adverse Events of Special Interest (AESI):

The following events will be considered as AESIs:

- Skin Lesions (regardless of its severity)
- Headaches (if lasts more than 72 hours AND is not resolved by standard painkillers)
- Anemia (Hemoglobin drop > 2 g/dL from baseline or Hemoglobin < 8g/dL)
- Hepatic enzymes (specifically, an increase ≥ 3.0 x ULN in liver transaminases (AST/SGOT and/or ALT/SGPT) or an increase ≥ 2.0 x ULN in in total bilirubin without initial findings of cholestasis (elevated alkaline phosphatase))
- Severe (grade ≥3) infections and opportunistic infections
- Acute pancreatic adverse events (an elevation of serum lipase and/or amylase at least three times greater than the upper limit of normal will be reported as AESI)
- Malignancies including Non-Melanoma Skin Cancers
- Cardiac AESIs: any AE with the SOC "cardiac disorders" (Aortic valve disease, Asystole, Atrial fibrillation, Atrial flutter, 3rd degree AV block (AV block complete), Cardiac arrest, Chest pain – cardiac, Heart failure, Left ventricular systolic dysfunction, Mitral valve disease, Mobitz (type) II atrioventricular block (type 2, 2nd degree AV block), Myocardial infarction, Myocarditis, Pericardial effusion, Pericardial tamponade, Pericarditis, Pulmonary valve disease, Restrictive cardiomyopathy, Right ventricular dysfunction, Sick sinus syndrome, Tricuspid valve disease, Ventricular fibrillation, Ventricular tachycardia.

Further definitions for the AESIs are described in protocol section 8.2.

Two periods will be defined for TEAE:

- Any adverse event which occurs or worsens from first dosing (BOLS) to the last dosing day;
- Any adverse event which occurs after the last dosing day.

Adverse events will be described by primary system organ class and preferred term. Numbers and percentage of subjects, and number of occurrences of adverse event will be presented for:

- AE (*Table 14.3.1.1)*;
- AE by severity (*Table 14.3.1.2)*;
- TEAE by relationship to study drug (*Table 14.3.1.3)*;
- TEAE leading to investigational product discontinuation (*Table 14.3.1.4)*;
- TEAE (*Table 14.3.1.5)*;
- TEAE by severity (*Table 14.3.1.6)*;
- Severe TEAE (grade 3 or 4) by relationship to study drug (*Table 14.3.1.7)*;
- Serious TEAE (*Table 14.3.1.8)*;
- TEAE of special interest (*Table 14.3.1.9)*;

All adverse events will be listed and the data will be tabulated by body system/organ class (N and percentage).

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.

The following will be presented in listing format within the data summaries:

- Deaths (*Table 14.3.2.1)*;
- Serious Adverse Events (*Table 14.3.2.2)*;
- Adverse Events which Led to Withdrawal (*Table 14.3.2.3)*.

Further definitions and procedures regarding adverse events are stated in the protocol (Section 8).

11.6.2 Laboratory Data

The absolute values of each laboratory parameter (Hematology, Biochemistry) will be summarised at each visit along with the change from baseline to each post baseline timepoint (*Table 14.3.3.1 and 14.3.3.2)*. In addition, shift tables from baseline to each post baseline timepoint will be presented (*Table 14.3.3.3 and 14.3.3.4)* to show Normal/ Abnormal Clinically Significant (CS)/ Abnormal Not Clinically Significant (NCS) results.

Laboratory data listings will be presented in two ways:

- Abnormal values (presented within the data summaries) (*Table 14.3.3.5)*

- All laboratory data (presented within the data listings)

If lab 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.

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

Serum pregnancy data will be listed only.

11.6.3 Vital Signs

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

The absolute values of the vital signs will be summarised at each visit by using descriptive statistics including the change from baseline to each post baseline timepoint (*Table 14.3.4)*.

11.6.4 Physical Examination

A routine physical examination (including body weight) will be done at each study visit. Physical examinations will cover eyes, ears, nose, throat, lungs/thorax, heart/cardiovascular system, abdomen, skin and mucosae, nervous system, lymph nodes, musculo-skeletal system, and, if applicable, others.

Shift tables will be presented showing changes from baseline to each post baseline visit for Normal / Abnormal NCS / Abnormal CS physical examination results (*Table 14.3.5)*.

11.6.5 Electrocardiogram

Electrocardiograms will be performed at Day 56, quarterly from M24 to M48 and at EoS visits.

The number and percentage of the patients with Normal / Abnormal NCS / Abnormal CS ECG results will be summarised for each visit (*Table 14.3.6)* along with the change from baseline to each post baseline timepoint.

11.7 Study Drug Exposure and Compliance

Treatment exposure (n, mean, SD, median, minimum and maximum) and compliance (%) will be summarised for the OC Set (*Table 14.3.7)*.

Dispensation details will be listed only.

11.8 Prior and Concomitant Medication

All medications taken by patients on entry to the study or during the study will be recorded in the CRF. Medications will be classified using the version of the World Health Organisation Drug Dictionary Enhanced (WHO-DDE) coding dictionary defined in the Data Management Plan. The Anatomical

Therapeutic Chemical (ATC) Classification and WHO-DRUG PT will be used to list and summarise the data.

Prior medications are defined as medication that started and stopped before Day 0. Only medications where the stop date is prior to Day 0 will be considered prior. If the stop date is unknown or incomplete and the medications cannot definitely be considered as stopped prior to Day 0 then the medications will be considered as concomitant medications at enrolment or change in concomitant medication, depending on the start date.

Concomitant medications at enrolment are defined as medications that started before Day 0 and either stopped on Day 0 or continued into the study. Partial start dates where the medication cannot definitely be considered as starting prior to Day 0 will lead to a categorisation of the medications as having started on or after dosing.

Change in concomitant medication is defined as medication that started on or after Day 0. If the medication start or stop dates are partial then the rules for prior and concomitant medication, detailed above will be observed prior to assigning a category.

The number (%) of patients reporting the use of any prior medications and the number (%) of patients taking each drug by ATC classification and PT will be summarised using the OC Set (*Table 14.3.8.1)*. This table will be repeated for concomitant medications at enrolment (*Table 14.3.8.2)* and for change in concomitant medication (*Table 14.3.8.3)*.

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 the lead programmer and lead statistician.

13 LITERATURE CITATIONS/REFERENCES

Not applicable.

14 LIST OF TABLES, FIGURES AND LISTINGS

14.1 LIST OF TABLES

Demographic Data

Table 14.1.1	Patient Disposition	All Enrolled Patients
Table 14.1.2	Study Termination and Primary Reason for Withdrawal	OC Set
Table 14.1.3	Demographic, Baseline and Disease Characteristics	OC Set
Table 14.1.4.1	Medical History	OC Set
Table 14.1.4.2	Current Medical Conditions	OC Set

Efficacy Data

Table 14.2.1.1	Change from Baseline: Mayo Score (MS, pMS, MMS and pMMS)	OC Set
Table 14.2.1.2	Change from Baseline: Mayo Score (MS, pMS, MMS and pMMS)	NRI Set
Table 14.2.1.3	Change from Baseline: Components of the Total Mayo Score	OC Set
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Table 14.2.2.1	Time to UC Worsening	OC Set
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Table 14.2.3.1	Change from Baseline: Faecal Calprotectin, CRP and ESR	OC Set
Table 14.2.3.2	Change from Baseline: Faecal Calprotectin, CRP and ESR	NRI Set
Table 14.2.4.1	Change from Baseline: SF-36 Questionnaire	OC Set
Table 14.2.4.2	Change from Baseline: SF-36 Questionnaire	NRI Set
Table 14.2.5.1	Proportion of Patients: Clinical Remission, Corticosteroid-free Clinical Remission and Clinical Response	OC Set
Table 14.2.5.2	Proportion of Patients: Clinical Remission, Corticosteroid-free Clinical Remission and Clinical Response	NRI Set
Table 14.2.5.3	Shift Table: Clinical Remission	OC Set
Table 14.2.5.4	Shift Table: Clinical Remission	NRI Set
Table 14.2.6.1	Proportion of Patients: Endoscopic Improvement and Endoscopic Remission	OC Set
Table 14.2.6.2	Proportion of Patients: Endoscopic Improvement and Endoscopic Remission	NRI Set

Table 14.2.7.1	Proportion of Patients: Sustained clinical remission and sustained endoscopic remission/improvement	OC Set
Table 14.2.7.2	Proportion of Patients: Sustained clinical remission and sustained endoscopic remission/improvement	NRI Set

Safety Data

Table 14.3.1.1	Adverse Events	OC Set
Table 14.3.1.2	Adverse Events by Severity	OC Set
Table 14.3.1.3	Treatment-Emergent Adverse Events by Relationship to Study Drug	OC Set
Table 14.3.1.4	Treatment-Emergent Adverse Events Leading to Investigational Product Discontinuation	OC Set
Table 14.3.1.5	Treatment-Emergent Adverse Events	OC Set
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Table 14.3.1.8	Severe TEAEs (grade 3 and 4) by Relationship to Study Drug	OC Set
Table 14.3.1.9	Treatment-Emergent Adverse Events of Special Interest	OC Set
Table 14.3.2.1	Listing of Deaths	OC Set
Table 14.3.2.2	Listing of Serious Adverse Events	OC Set
Table 14.3.2.3	Listing of Adverse Events Leading to Withdrawals	OC Set
Table 14.3.3.1	Change from Baseline of Laboratory Parameters: Hematology	OC Set
Table 14.3.3.2	Change from Baseline of Laboratory Parameters: Biochemistry	OC Set
Table 14.3.3.3	Shift Table of Laboratory Parameters: Hematology	OC Set
Table 14.3.3.4	Shift Table of Laboratory Parameters: Biochemistry	OC Set
Table 14.3.3.5	Listing of Abnormal Laboratory Values	OC Set
Table 14.3.4	Vital Signs	OC Set
Table 14.3.5	Physical Examination	OC Set
Table 14.3.6	Electrocardiogram	OC Set
Table 14.3.7	Study Drug Exposure and Compliance	OC Set
Table 14.3.8.1	Prior Medications	OC Set
Table 14.3.8.2	Concomitant Medications	OC Set
Table 14.3.8.3	Changes in Concomitant Medications	OC Set

14.2 List of Figures

Not applicable.

14.3 List of Listings

Patient Data Listings

Listing 16.2.1	Patient Visit Dates
Listing 16.2.2	Patient Disposition
Listing 16.2.3	Analysis Datasets and Subgroups
Listing 16.2.4.1	Demographic, Baseline and Disease Characteristics Data
Listing 16.2.4.2	Medical History
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Listing 16.2.9.3	Changes to Medications
Listing 16.2.10	Procedures

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:

  ABX464-102 (left); date ddMMMyyyy HH:MM (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 will be included in all listings.

ABX464-102 ddMMMyyyy HH:MM

Table 14.1.1 Patient Disposition (All Enrolled Patients)

	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
OC Set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
NRI Set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

The denominator for each percentage is the number of patients in the column.
OC = Observed Cases, NRI = Non-responder Imputation.

Source: Listing 16.2.3
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ABX464-102 ddMMMyyyy HH:MM

Table 14.1.2 Study Termination and Primary Reason for Withdrawal (OC Set)

	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=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%)
Worsening of UC	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%)
Etc			

The denominator for each percentage is the number of patients in the column. Completed defined as performed follow-up visit.

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Table 14.1.3 Demographic, Baseline and Disease Characteristics (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (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
Gender	n	xx	xx	xx
	Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Childbearing*	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for non-Childbearing*	Post-menopausal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Surgically Sterile	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
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%)
	Etc			
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
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
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
Modified 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
Faecal calprotectin (unit)	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
Number of subjects with concomitant Corticosteroid	N (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Clinical remission	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Corticosteroid-free clinical remission	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Clinical response	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Endoscopic remission	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Endoscopic improvement	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
Age was calculated using Year of Birth and date of first treatment 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 meters.
*The denominator is the total number of females within the column.

Source: Listing 16.2.4.1
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ABX464-102 ddMMMyyyy HH:MM

Table 14.1.4.1 Medical History (OC Set)

	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (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			
SOC	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc			
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.
MedDRA version <XX.X>.

Source: Listing 16.2.4.2
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This layout also applies to:
*Table 14.1.4.2 Current Medical Conditions (*OC Set*) [Programming Note: Update second footnote to current medical conditions: 'Current medical condition refers to conditions that are ongoing at the screening visit.']*

ABX464-102 ddMMMyyyy HH:MM

Table 14.2.1.1 Change from Baseline: Mayo Score (MS, pMS, MMS and pMMS) (OC Set)

<Subgroups>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Total Mayo Score (MS)*				
BIS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	95% CI	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Quartiles	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
BOLS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Etc			
Change from BIS to BOLS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Etc			
Change from BIS to Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			

Change from BOLS to Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Etc				
Partial Mayo Score (pMS)				
Etc				
Modified Mayo Score (MMS)*				
Etc				
Partial Modified Mayo Score (pMMS)				
Etc				

*Total Mayo Score and Modified Mayo Score are only collected at visits where an endoscopy is carried out.
The denominator for each percentage is the number of patients within the column.
BIS: Day 0 of ABX464-101 study
BOLS: Day 56 of ABX464-101 study

Source: Listing 16.2.6.1
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Programming Note: Include Total Mayo Scores and Partial Mayo Scores.
Please present subgroups in the following order:

- *All patients*
- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*

- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

This layout also applies to:
Table 14.2.1.2 Change from Baseline: Mayo Score (MS, pMS, MMS and pMMS) (NRI Set)
*Table 14.2.1.3 Change from Baseline: Components of the Total Mayo Score (*OC Set*)*
Table 14.2.1.4 Change from Baseline: Components of the Total Mayo Score (NRI Set)

Programming Note for Table 14.2.1.3 and 1.4: Components: Stool frequency, Rectal bleeding, Physician rating of disease activity and Mucosal appearance at endoscopy – central reading

ABX464-102 ddMMMyyyy HH:MM

Table 14.2.2.1 Time to UC Worsening (OC Set)

<Subgroup>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Time to UC worsening from BIS (Unit)	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	95% CI	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Quartiles	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
Time to UC worsening from BOLS (Unit)	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	95% CI	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Quartiles	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx

BIS: Day 0 of ABX464-101 study
BOLS: Day 56 of ABX464-101 study

Source: Listing 16.2.6.2
Path\Filename

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Programming Note: Please present subgroups in the following order:

- *All patients*
- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

This layout also applies to:
Table 14.2.2.2 Time to UC Worsening (NRI Set)

Table 14.2.3.1 Change from Baseline: Faecal Calprotectin, CRP and ESR (OC Set)

<Subgroup>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Parameter				
BIS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	95% CI	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Quartiles	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
BOLS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Etc			
Change from BIS to BOLS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Etc			
Change from BIS to Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			

Change from BOLS to Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Etc				

The denominator for each percentage is the number of patients within the column.
BIS: Day 0 of ABX464-101 study
BOLS: Day 56 of ABX464-101 study

Source: Listing 16.2.6.3
Path\Filename

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Programming Note: Parameters to be included: Faecal Calprotectin, CRP and ESR.
Please present subgroups in the following order:

- *All patients*
- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

This layout also applies to:
Table 14.2.3.2 Change from Baseline: Faecal Calprotectin, CRP and ESR (NRI Set)

Table 14.2.4.1 Change from Baseline: SF-36 Questionnaire (OC Set)

<Subgroup>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
BIS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	95% CI	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
	SD	xx.xx	xx.xx	xx.xx
	Minimum	xx.x	xx.x	xx.x
	Maximum	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Quartiles	xx.xx – xx.xx	xx.xx – xx.xx	xx.xx – xx.xx
BOLS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Etc			
Change from BIS to BOLS	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Missing	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Etc			
Change from BIS to Visit	n	xx (xx.x %)	xx (xx.x %)	xx (xx.x %)
	Mean	xx.xx	xx.xx	xx.xx
	Etc			

Change from BOLS to Visit	n Mean Etc	xx (xx.x %) xx.xx	xx (xx.x %) xx.xx	xx (xx.x %) xx.xx
Etc				

The denominator for each percentage is the number of patients within the column.
SF-36 Questionnaire was assessed up to M24 visit.
BIS: Day 0 of ABX464-101 study
BOLS: Day 56 of ABX464-101 study

Source: Listing 16.2.6.4
Path\Filename

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Programming Note: Please present subgroups in the following order:

- *All patients*
- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

This layout also applies to:
Table 14.2.4.2 Change from Baseline: SF-36 Questionnaire (NRI Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.2.5.1 Proportion of Patients: Clinical Remission, Corticosteroid-free Clinical Remission and Clinical Response (OC Set)

<Subgroup>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Clinical Remission				
Visit	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc				
Clinical Response				
Visit	n	xx	xx	xx
	Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc				
Clinical Response				
Etc				

The denominator for each percentage is the number of patients within the column.

Source: Listing 16.2.6.1
Path\Filename

Programming Note: Please present subgroups in the following order:

- *All patients*
- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

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This layout also applies to:
Table 14.2.5.2 Proportion of Patients: Clinical Remission, Corticosteroid-free Clinical Remission and Clinical Response (NRI Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.2.5.3 Shift Table: Clinical Remission (OC Set)

<Subgroup>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
BIS	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
BOLS	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change from BIS to BOLS	Yes -> Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes -> No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Visit	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change from BIS to Visit	Yes -> Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes -> No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Change from BOLS to Visit	Yes -> Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Yes -> No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Etc				

The denominator for each percentage is the number of non-missing observations within the column.
BIS: Day 0 of ABX464-101 study

BOLS: Day 56 of ABX464-101 study

Source: Listing 16.2.6.1
Path\Filename

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Programming Note: Please present subgroups in the following order:

- *All patients*
- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

This layout also applies to:
Table 14.2.5.4 Shift Table: Clinical Remission (NRI Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.2.6.1 Proportion of Patients: Endoscopic Improvement and Endoscopic Remission (OC Set)

<Subgroup>

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Endoscopic Improvement				
Visit	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc				
Endoscopic Remission				
Visit	n	xx	xx	xx
	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Missing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc				

The denominator for each percentage is the number of patients within the column.
Endoscopic Improvement and Endoscopic Remission are based on central reading endoscopy.

Source: Listing 16.2.6.1
Path\Filename

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Programming Note: Please present subgroups in the following order:

- *All patients*

- *Patients being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients not being in clinical response at Baseline Open-Label Study (BOLS)*
- *Patients previously treated with biological drugs*
- *Patients naive from biological drugs*

This layout also applies to:
Table 14.2.6.2 Proportion of Patients: Endoscopic Improvement and Endoscopic Remission (NRI Set)
Table 14.2.7.1 Proportion of Patients: Sustained clinical remission and sustained endoscopic remission/improvement (OC Set)
Table 14.2.7.2 Proportion of Patients: Sustained clinical remission and sustained endoscopic remission/improvement (NRI Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.3.1.1 Adverse Events (OC Set)

Period X

	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
	E n (%)	E n (%)	E 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%)
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%)
Any Adverse Event leading to death	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
Any Treatment-Emergent Adverse Event of Special Interest	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)

The table presents number of events (E) and number and percentage of patients (n(%)).
The denominator for each percentage is the number of patients within the column.
MedDRA version <XX.X>.
Period 1: Any adverse event which occurs or worsens from first dosing to the last dosing day. Period 2: Any adverse event which occurs after the last dosing day.

Source: Listing 16.2.7
Path\Filename

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Programming Note: Please present for both periods with the number of the period in the header (Period X).

This layout also applies to:
Table 14.3.1.4 Treatment-Emergent Adverse Events Leading to Investigational Product Discontinuation (OC Set)
Table 14.3.1.5 Treatment-Emergent Adverse Events (OC Set)

Table 14.3.1.7 Serious Treatment-Emergent Adverse Events (OC Set)
Table 14.3.1.9 Treatment-Emergent Adverse Events of Special Interest (OC Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.3.1.2 Adverse Events by Severity (OC Set)

Period X

	Severity	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
		E n (%)	E n (%)	E n (%)
Any Adverse Events		xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
SOC	Grade 1	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
	Grade 3	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
PT	Grade 1	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
PT	Grade 1	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
	Grade 3	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
Etc				
Etc				

The table presents number of events (E) and number and percentage of patients (n(%)).
The denominator for each percentage is the number of patients within the column.
MedDRA version <XX.X>.
Period 1: Any adverse event which occurs or worsens from first dosing to the last dosing day. Period 2: Any adverse event which occurs after the last dosing day.

Source: Listing 16.2.7
Path\Filename

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Programming Note: Please present for both periods with the number of the period in the header (Period X). Only present severity categories with at least 1 non-missing value.

This layout also applies to:
Table 14.3.1.6 Treatment-Emergent Adverse Events by Severity (OC Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.3.1.3 Treatment-Emergent Adverse Events by Relationship to Study Drug (OC Set)

Period X

	Relationship to Study Drug	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
		E n (%)	E n (%)	E n (%)
Any Adverse Event		xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
SOC	Not related	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
	Related	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
PT	Related	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
PT	Not related	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
	Related	xx xx (xx.x%)	xx xx (xx.x%)	xx xx (xx.x%)
Etc				
Etc				

The table presents number of events (E) and number and percentage of patients (n(%)).
The denominator for each percentage is the number of patients within the column.
MedDRA version <XX.X>.
Period 1: Any adverse event which occurs or worsens from first dosing to the last dosing day. Period 2: Any adverse event which occurs after the last dosing day.

Source: Listing 16.2.7
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Programming Note: Please present for both periods with the number of the period in the header (Period X). Only present categories with at least 1 non-missing value.

This layout also applies to:
Table 14.3.1.8 Severe TEAEs (grade 3 and 4) by relationship to study drug (OC Set)

ABX464-102 ddMMMyyyy HH:MM

Table 14.3.2.1 Listing of Deaths (OC Set)

Treatment	Centre/ Patient number	Date of death	Cause of death	Period
xxxxxx	xxxx-xxx	ddMMMyyyy HH:MM	xxxxxxxxxxxxxxxxxx	Period 1/ Period 2
xxxxxx	xxxx-xxx	ddMMMyyyy HH:MM	xxxxxxxxxxxxxxxxxx	Period 1/ Period 2
Etc				

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ABX464-102 ddMMMyyyy HH:MM

Table 14.3.2.2 Listing of Serious Adverse Events (OC Set)

Treatment	Centre/ Patient number	Adverse Event PT SOC	Onset date	Resolution date / ongoing	Outcome	Relationship to study drug	Action taken with study drug	Other action taken	Period
xxxxx	xxxx-xxx	xxxxxxxxxx xxxxxxxx xxxx Etc	ddMMMyyyy HH:MM	ddMMMyyyy HH:MM / ongoing	Resolved/ Resolved without sequelae/ Etc	Related/ Not related	None/ Temporary discontinuation/ Etc	Concomitant medication (CM no.)/ Procedure (PR no.)	Period 1/ Period 2
Etc									

MedDRA version <XX.X>.
Period 1: Any adverse event which occurs or worsens from first dosing to the last dosing day. Period 2: Any adverse event which occurs after the last dosing day .

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This layout also applies to:
Table 14.3.2.3 Listing of Adverse Events Leading to Withdrawals (OC Set)

Table 14.3.3.1 Change from Baseline of Laboratory Parameters: Hematology (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Parameter				
Baseline	n	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	SEM	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
Visit	n	Xx	Xx	Xx
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Change from Baseline to Visit	n	Xx	Xx	Xx
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Etc				
Etc				

Source: Listing 16.2.8.1
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Programming Note: start each parameter on a new page

This layout also applies to:
Table 14.3.3.2 Change from Baseline of Laboratory Parameters: Biochemistry (OC Set) [Source: Listing 16.2.8.2]

ABX464-102 ddMMMyyyy HH:MM

Table 14.3.3.3 Shift Table of Laboratory Parameters: Hematology (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Parameter				
Baseline	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change from Baseline to Visit	Normal -> Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Etc				
Etc				

The denominator for each percentage is the number of non-missing observations within the column.
NCS = Not Clinically Significant; CS = Clinically Significant.

Source: Listing 16.2.8.1
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Programming Note: start each parameter on a new page

This layout also applies to:

Table 14.3.3.4 Shift Table of Laboratory Parameters: Biochemistry (OC Set) [Source: Listing 16.2.8.2]

ABX464-102 ddMMMyyyy HH:MM

Table 14.3.3.5 Listing of Abnormal Laboratory Values (OC Set)

Treatment	Centre/ Patient number	Visit	Laboratory Parameter	Result	Unit	Reference range	Interpretation
xxxxxx	xxxx-xxx	Week x	xxxxxxxxxxxxxxxxxx	xx.xx	xx	xx.xx – xx.xx	Normal/ Abnormal CS/ Abnormal NCS
			xxxxxxxxxxxxxxxxxx	xx.xx	xx	<xx.xx	Normal/ Abnormal CS/ Abnormal NCS
			Etc				
		Etc					
	Etc						
Etc							

NCS = Not Clinically Significant; CS = Clinically Significant.

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ABX464-102 ddMMMyyyy HH:MM

Table 14.3.4 Vital Signs (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Parameter				
Baseline	n	xx	xx	xx
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	SEM	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
Visit	n	Xx	Xx	Xx
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Change from Baseline to Visit	n	Xx	Xx	Xx
	Mean	xx.xx	xx.xx	xx.xx
	Etc			
Etc				
Etc				

Source: Listing 16.2.8.3
Path\Filename

Programming Note: start each parameter on a new page. List of variables: body temperature, systolic and diastolic blood pressure, heart rate and weight.

Table 14.3.5 Physical Examination (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Parameter/Body system				
Baseline	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change from Baseline to Visit	Normal -> Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Etc				
Etc				

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

NCS = Not Clinically Significant; CS = Clinically Significant.

Source: Listing 16.2.8.4
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Programming Note: start each parameter on a new page

Table 14.3.6 Electrocardiogram (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Baseline	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal NCS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit	Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change from Baseline to Visit	Normal -> Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Normal -> Abnormal CS	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Etc			
Etc				

The denominator for each percentage is the number of non-missing observations within the column.
NCS = Not Clinically Significant; CS = Clinically Significant.

Source: Listing 16.2.8.5
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ABX464-102 ddMMMyyyy HH:MM

Table 14.3.7 Study Drug Exposure and Compliance (OC Set)

		50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (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			
Compliance (%)	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 16.2.5
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Table 14.3.8.1 Prior Medications (OC Set)

	50mg ABX464 (101) + 50mg ABX464 (102) (N=xx)	Placebo (101) + 50mg ABX464 (102) (N=xx)	Total (N=xx)
Any prior medications	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
X, xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
X0N, xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
X0NXX, xxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
xxxxxxxxxxxxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
X0NXX, 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%)
Etc			
Etc			

Prior medications are defined as medication that has started and stopped before first dose.
WHO-DDE version <XXXX>.
Data are summarized by: Anatomical main group (ATC level 1); Therapeutic subgroup (ATC level 2); Therapeutic/pharmacological subgroup (ATC level 3); Chemical/therapeutic/pharmacological subgroup (ATC level 4); Preferred term.
The denominator for each percentage is the number of patients within the column.

Source: Listing 16.2.9.1
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This layout also applies to:
Table 14.3.8.2 Concomitant Medications (OC Set) (first footnote to be changed: Concomitant medications are defined as medications that started before first dose and either stopped on Day 1 or continued into the study.) [Source: Listing 16.2.9.2]
Table 14.3.8.3 Changes in Concomitant Medications (OC Set) (first footnote to be changed: Change in concomitant medication is defined as medication that started on or after first dose.) [Source: Listing 16.2.9.3]

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.1 Patient Visit Dates

Treatment	Centre/ Patient number	Visit	Date	Reason for Unscheduled Visit
xxxxxx	xxxx-xxx	xx	ddMMMyyyy	
		xx	ddMMMyyyy	xxxxxxxxxxxxxxxxxxxxxxxxxxx
		xx*	ddMMMyyyy	
		xx	ddMMMyyyy	
Etc				

*Outside the visit window

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.2 Patient Disposition

Treatment	Centre/ Patient number	Consent date	Reconsent date	First dose date	Last dose date	Completed study	Date of completion/ withdrawal	If not completed specify	Death date
xxxxxx	xxxx-xxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Yes/No	ddMMMyyyy	specify	ddMMMyyyy
	xxxx-xxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Yes/No	ddMMMyyyy	specify	ddMMMyyyy
	xxxx-xxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Yes/No	ddMMMyyyy	specify	
	xxxx-xxx	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Yes/No	ddMMMyyyy	specify	
Etc									

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.3 Analysis Datasets and Subgroups

Treatment	Centre/ Patient number	OC Set	NRI Set	Subgroup: patients being in clinical response at Baseline Open Label Study (BOLS)	Subgroup: patients previously treated with biological drugs
xxxxxx	xxxx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
	xxxx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
	xxxx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
	xxxx-xxx	Yes/No	Yes/No	Yes/No	Yes/No
Etc					

OC = Observed Cases, NRI = Non-responder Imputation.

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.4.1 Demographic, Baseline and Disease Characteristics Data – (1)

Treatment	Centre/ Patient number	Year of birth	Age (years)	Gender	Race	Weight (kg)	Height (cm)	BMI (kg/m^2)
xxxxxx	xxxx-xxx	yyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxxx-xxx	yyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxxx-xxx	yyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxxx-xxx	yyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
	xxxx-xxx	yyyy	xx	xxxx	xxxx	xx.x	xxx.x	xx.x
Etc								

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Programming Note: Please include (1) and (2) pages in one rtf, for every (1) page there will be a consecutive (2) page.
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.4.1 Demographic, Baseline and Disease Characteristics Data – (2)

Treatment	Centre/ Patient number	Mayo Score	Faecal calprotectin (unit)	Clinical remission	Clinical response	Endoscopic remission	Endoscopic improvement
xxxxxx	xxxx-xxx	xx	xx	Y/N	Y/N	Y/N	Y/N
	xxxx-xxx	xx	xx	Y/N	Y/N	Y/N	Y/N
	xxxx-xxx	xx	xx	Y/N	Y/N	Y/N	Y/N
	xxxx-xxx	xx	xx	Y/N	Y/N	Y/N	Y/N
	xxxx-xxx	xx	xx	Y/N	Y/N	Y/N	Y/N
Etc							

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Programming Note: Please include (1) and (2) pages in one rtf, for every (1) page there will be a consecutive (2) page.
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.4.2 Medical History

Treatment	Centre/ Patient number	Condition SOC PT	Date of diagnosis	Ongoing (End date)
xxxxxx	xxxx-xxx	xxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxx	ddMMMyyyy ddMMMyyyy 	Yes/ No (ddMMMyyyy) Yes/ No (ddMMMyyyy)
Etc				

MedDRA version <XX.X>.

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.4.3 Pregnancy Results

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

*Outside the visit window

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.4.4 Inclusion Criteria

Protocol version: XXXX

	Definition of criterion
1	xxxxxxxxxxxxxxxx
2	xxxxxxxxxxxxxxxx
3	Etc
4	
5	
6	
7	
8	
Etc	

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Programming Note: The list of criteria will be presented on the first page of the listing. Patient data will start on page 2. Repeat for each protocol amendment if the criteria change.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.4.4 Inclusion Criteria

Treatment	Centre/ Patient number	Protocol version	Criteria								
			1	2	3	4	5	6	7	8	Etc
xxxxxx	xxxx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
	xxxx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
	xxxx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
	xxxx-xxx	xxxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
Etc											

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

This layout also applies to:
Listing 16.2.4.5 Exclusion Criteria

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.5 Study Drug Exposure and Compliance

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

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.6.1 Efficacy Data: Mayo Score and components – (1)

Treatment	Centre/ Patient number	Visit	Stool frequency subscore	Rectal bleeding subscore	Physician's Global Assessment subscore	Central reading Endoscopy subscore	Local reading Endoscopy subscore	Clinical Remission	Corticosteroid -free clinical remission	Clinical Response
xxxxxx	xxxx-xxx	Visit	xx	xx	xx	xx	xx	Y/N	Y/N	Y/N
		Etc*								
Etc										

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*Programming Note: Please include "*Outside the visit window" footnote if applicable. Please include (1) and (2) pages in one rtf, for every (1) page there will be a consecutive (2) page. For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.*

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.6.1 Efficacy Data: Mayo Score and components – (2)

Treatment	Centre/ Patient number	Visit	Endoscopic Improvement	Endoscopic Remission	Total Mayo Score (TMS)	Partial Mayo Score (pMS)	Modified Mayo Score (MMS)	Partial Modified Mayo Score (pMMS)
xxxxxx	xxxx-xxx	Visit	Y/N	Y/N	xx	xx	xx	xx
		Etc*						
Etc								

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*Programming Note: Please include "*Outside the visit window" footnote if applicable. Please include (1) and (2) pages in one rtf, for every (1) page there will be a consecutive (2) page. For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.*

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.6.2 Efficacy Data: Time to UC Worsening

Treatment	Centre/ Patient number	Time to UC worsening (unit)	
		from BIS	from BOLS
xxxxxx	xxxx-xxx	xx	xx
Etc			

BIS: Day 0 of ABX464-101 study
BOLS: Day 56 of ABX464-101 study

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.6.3 Efficacy Data: Faecal Calprotectin, CRP and ESR

Treatment	Centre/ Patient number	Visit	Faecal Calprotectin (unit)	CRP (unit)	ESR (unit)
xxxxxx	xxxx-xxx	Baseline	xx	xx	xx
		Etc*			
Etc					

*Outside the visit window

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.6.4 Efficacy Data: SF-36 Questionnaire

Treatment	Centre/ Patient number	Visit	Question	Result
xxxxxx	xxxx-xxx	Baseline	In general, would you say your health is:	1. Excellent/ 2. Very good/ 3. Good/ 4. Fair/ 5. Poor
			Compared to one year ago, how would you rate your health in general now?	Etc
			Etc	
			Total Score	xx
		Etc*		
Etc				

*Outside the visit window

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.7 Adverse Event Listing

Treatment	Centre/ Patient number	Adverse Event SOC PT	Onset date	Resolution date /ongoing	Outcome	Serious	Severity	Relationship to study drug	Action taken with study drug	Other action taken	Period
xxxxxxx	xxxx-xxx	xxxxxxxxx xxxxxxxx xxxxxxx	ddMMMyyyy	ddMMMyyyy/ Ongoing	Resolved/resolved without sequelae /Etc	Yes /No	Grade 1/ Grade 2/ etc	Related/ Not related	None /Temporary discontinuation /Etc	Concomitant medication (CM no.)/ Procedure (PR No.)	Period 1/ Period 2
		xxxxxxxxx xxxxxxxx xxxxxxx	ddMMMyyyy	ddMMMyyyy/ Ongoing	Resolved/resolved without sequelae /Etc	Yes /No	Grade 1/ Grade 2/ etc	Related/ Not related	None /Temporary discontinuation /Etc	Concomitant medication (CM no.)/ Procedure (PR No.)	Period 1/ Period 2
		Etc									
Etc											

MedDRA version <XX.X>.
Period 1: Any adverse event which occurs or worsens from first dosing to the last dosing day. Period 2: Any adverse event which occurs after the last dosing day.

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

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Listing 16.2.8.1 Laboratory Measurements: Hematology

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

*Outside the visit window
CS=Clinically Significant; NCS=Not Clinically Significant

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

This layout also applies to:
Listing 16.2.8.2 Laboratory Measurements: Biochemistry

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.8.3 Vital Signs

Treatment	Centre/ Patient number	Visit	Body Temperature (°C)	Weight (kg)	Height (cm)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Heart rate (beats/min)	Review
xxxxxx	xxxx-xxx	xx	xx.x	xx.x	xxx	xxx	xxx	xxx	Normal/ Abnormal CS/ Abnormal NCS
		xx	xx.x	xx.x	xxx	xxx	xxx	xxx	Normal/ Abnormal CS/ Abnormal NCS
		xx*	xx.x	xx.x	xxx	xxx	xxx	xxx	Normal/ Abnormal CS/ Abnormal NCS
		xx	xx.x	xx.x	xxx	xxx	xxx	xxx	Normal/ Abnormal CS/ Abnormal NCS
Etc									

*Outside the visit window
CS=Clinically Significant; NCS=Not Clinically Significant

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.8.4 Physical Examination

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

*Outside the visit window
CS=Clinically Significant; NCS=Not Clinically Significant

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

Listing 16.2.8.5 12-Lead Electrocardiogram

Treatment	Centre/ Patient number	Visit	Investigator's interpretation
xxxxxx	xxxx-xxx	Visit	Normal/ Abnormal NCS/ Abnormal CS
		Visit	Normal/ Abnormal NCS/ Abnormal CS
		Etc*	
	Etc		
Etc			

*Outside the visit window
CS=Clinically Significant; NCS=Not Clinically Significant

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.8.6 Echocardiography

Treatment	Centre/ Patient number	Visit	Parameter	Result	Unit
xxxxxxx	xxxx-xxx	Visit	Parameter	xxx.xx	xxxx
			Etc	xxx.xx	xxxx
			Interpretation	Normal/ Abnormal CS/ Abnormal NCS	
		Etc*			
	xxxx-xxx	Visit	Parameter	xxx.xx	xxxx
			Etc		
	Etc				
Etc					

*Outside the visit window
CS=Clinically Significant; NCS=Not Clinically Significant

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*Programming Note: Please include "*Outside the visit window" footnote if applicable.*
For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.9.1 Prior Medications

Treatment	Centre/ Patient number	Therapy ATC Code PT	Indication	Dose	Unit	Frequency	Route	Start date (Stop date / Ongoing)	Given for pre-existing condition? (Related medical history number)	Given for adverse event? (Related adverse event number)	Given for procedure/non-drug therapy? (Related procedure number)
xxxxxx	xxxx-xxx	xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	xxxxxxx	xx.x	xxx	xxx	xxx	ddMMMyyyy (ddMMMyyyy)	Yes (xxx) / No	Yes (xxx) / No	Yes (xxx) / No
		xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	xxxxxxx	xx.x	xxx	xxx	xxx	ddMMMyyyy (ddMMMyyyy)	Yes (xxx) / No	Yes (xxx) / No	Yes (xxx) / No
		xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	xxxxxxx	xx.x	xxx	xxx	xxx	ddMMMyyyy (ddMMMyyyy)	Yes (xxx) / No	Yes (xxx) / No	Yes (xxx) / No
Etc											

Prior medications are defined as medication that has started and stopped before first dose.
WHO-DDE version <XXXX>.

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

This layout also applies to:
Listing 16.2.9.2 Concomitant Medications (first footnote to be changed: Concomitant medications are defined as medications that started before first dose and either stopped on Day 1 or continued into the study.)
Listing 16.2.9.3 Changes to Medications (first footnote to be changed: Change in concomitant medication is defined as medication that started on or after first dose.)

ABX464-102 ddMMMyyyy HH:MM

Listing 16.2.10 Procedures

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

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Programming Note: For the Treatment column, please present treatment for ABX101 + ABX102 study consistently to the table headers.

16 APPENDICES

16.1 STUDY SCHEDULE

	(D56) D0	*D7*	*D14*	*D21*	*D28*	*D42*	*Day56/M2*	*Mx+1 to M24*	*M27 to M45**	*M48*	*EoS*
Time Window		± 2 days	± 2 days	± 2 days	± 4 days	± 2 days	± 4 days	± 4 days	± 14 days	± 14 days	28 days after ABX464 Stop (± 4 days)
ABX464-101 D56 examinations	X										
Obtained Inform Consent	X										
Check of IN/EX Criteria	X										
Physical Examination		X	X	X	X	X	X	X	X	X	X
Body Weight (kg)		X	X	X	X	X	X	X	X	X	X
Vital signs		X	X	X	X	X	X	X	X	X	X
ECG (12 lead)							X	At Month 24	X	X	X
Blood Pregnancy test (WOCBP)					X		X	X	X[a]	X[a]	X
Hematology + Biochemistry, including NT-proBNP[b]		X	X	X	X	X	X	X	X[b]	X[b]	X[b]
miR-124 blood sample (Paxgene®)								At Month 12	At Month 36	At Month 48	
Mayo score (Total or Partial)		X	X	X	X	X	X	X	X	X	X
Faecal calprotectin					X		X	X	X	X	X
Sigmoidoscopy					As needed		X	At Month 24	At Month 36	At Month 48[d]	
Cardiac ischemic disease/congestive heart failure medical/treatment history review									X	X	
Echocardiography[c]									X	X	
SF-36 (Questionnaire)					X		X	X			
ABX464 treatment dispensation	X				X		X	X	X		
Adverse Events and CM recording	X	X	X	X	X	X	X	X	X	X	X

* Visits are performed quarterly after M24 (at M27, M30, M33, M36, M39, M42, M45, M48).

[a] Urine pregnancy tests will be provided to WOCBP to perform a pregnancy check every month (between onsite visits)

[b] NT-proBNP blood levels only at Month 42 and 48 and at the End of Study Visit
[c] Echocardiography at the earliest visit, then at Month 42 and 48
[d] Local reading result of sigmoidoscopy need to be available on M48 visit to check eligibility to enter study ABX464-108