

STATISTICAL ANALYSIS PLAN



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Protocol Title:	A Phase II/III Randomized, Double-blind, Placebo-controlled, Multicenter Study to Determine the Efficacy and Safety of ABC008 in the Treatment of Subjects with Inclusion Body Myositis
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VERSION HISTORY

SAP Version	Version Date	Change(s)	Rationale
1.0	31 July 2025	Initial version	
2.0	23 Nov 2025	Addition of descriptive text related to dynamometry measures in both key secondary efficacy objectives and endpoints. Clarified the testing strategy alpha split between the two dose-placebo comparisons.	Providing clarity on the key secondary efficacy endpoints. Updated testing strategy (allocating more alpha to the high-dose group) to reflect FDA feedback from the Type C Meeting (March 2025).
3.0	9 Jan 2026	Updated the definition of the per-protocol analysis set in Section 3 and Section 7	The per-protocol analysis set has been aligned with the protocol

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Term
AE	Adverse Event
AESI	Adverse Event of Special Interest
ANCOVA	Analysis of covariance
Anti-cN-1A	Anti-cytosolic 5'-nucleotidase 1A
ATC	Anatomic Therapeutic Classification
DSMB	Data and Safety Monitoring Board
eCRF	Electronic Case Report Form
IBM	Inclusion Body Myositis
IBMFRS	IBM Functional Rating Scale
ICE	Intercurrent Event
MAR	Missingness at Random
MedDRA	Medical Dictionary for Regulatory Activities
MI	Multiple Imputation
MMT	Manual Muscle Testing
mTUG	Modified Timed Up and Go Test
PK	Pharmacokinetic
PR	Partial Response
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Stable Disease
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
WHO	World Health Organization

1. INTRODUCTION

This Statistical Analysis Plan provides analyses details for Protocol ABC008-IBM-201, Amendment 6. This analysis plan is meant to supplement the study protocol. If differences occur between analyses described in the SAP and the current protocol, those found in this SAP will assume primacy. Any deviations from this plan will be described in the Clinical Study Report. The ICH guideline E3 “Structure and Content of Clinical Trial Reports” was used as a guide to the writing of the plan.

2. TRIAL DESIGN AND ENDPOINTS

2.1. Trial Design

This is a Phase II/III randomized, double-blind, placebo-controlled, parallel, multicenter study with three parts:

- Part A is the sentinel safety cohort in which subjects will receive three doses of study drug and the resultant safety and tolerability data will be evaluated by a Data and Safety Monitoring Board (DSMB). With a favorable DSMB review, the study will progress to Part B.
- Part B is the main phase of the trial aimed at evaluating the efficacy, safety, and tolerability of two dose levels, 0.5 mg/kg and 2.0 mg/kg of ABC008 compared with placebo in subjects with IBM.
- Part C is the PD and safety follow-up to follow recovery of the depletion of KLRG1+ cells after end of treatment is completed.

Part A (Sentinel Cohort) of the study comprises an up to five-week Screening Period, a 76-week Treatment Period (including 20 weeks of sentinel dosing followed by a DSMB review to determine continued dosing through the end of the Treatment Period), and safety follow-up four weeks after the Week 76 visit (eight weeks after the last dose at Week 72 in the Treatment Period). Part A will be double-blind and placebo-controlled. Approximately 30 eligible subjects in Part A will be randomized in a 2:2:1 ratio to one of two dose levels of ABC008 or matching placebo. The study drug will be dosed via SC injection every eight weeks. After subjects have received three doses of study drug, a DSMB will review the interim safety data for all Part A subjects through at least the Week 20 visit. Subjects may continue in their assigned groups in a double-blind manner while the DSMB sentinel cohort review is pending. Continued dosing of Part A subjects through Week 72 will be predicated on a favorable DSMB assessment of safety, as will initiation of enrollment in Part B.

Part B (Double-Blind Safety and Efficacy Cohort) of the study comprises an up to five-week Screening Period, a 76-week Treatment Period, and safety follow-up four weeks after the Week 76 visit (eight weeks after the last dose). Part B will be double-blind and placebo controlled. Approximately 200 eligible subjects in Part B will be randomized in a 1:1:1 ratio to one of two dose levels of ABC008 or matching placebo. The study drug will be dosed via SC injection Q8W.

In both Part A and Part B, at the Week 80 visit, subjects will be eligible to enroll in an open-label long-term extension study. The Week 80 visit is intended to serve both as a safety follow-up visit for Part A or B of the current study and the Baseline Visit for the long-term extension study.

Subjects who choose not to enroll in the open-label long-term extension study and subjects who prematurely discontinue study drug during Part A or B will progress to Part C (PD Recovery Cohort) for follow up. The Part A or B Week 80 visit is intended to serve as the Baseline Visit for Part C. Part C of the study will consist of adverse event follow-up monthly, PD assessments and pregnancy testing every three months. The Follow-up Period in Part C will be a minimum of three months and will continue for each subject until their KLRG1+ cells have recovered. This will be performed by flow cytometry. All subjects entering Part A and B will have baseline flow cytometry performed and subjects entering Part C will have flow cytometry performed every three months until recovery. Once KLRG1+ cell recovery has been documented, an End-of-Study phone call will be conducted to notify the subject and collect any AEs not previously reported.

2.2. Efficacy Endpoints (Part A and Part B)

2.2.1. Primary Efficacy Endpoint

- Mean change from baseline in the IBMFRS total score at Week 76.

2.2.2. Key Secondary Efficacy Endpoints

The following key secondary efficacy endpoints will be analyzed in a sequential manner:

1. Mean change from baseline in the MMT-12 total score at Week 76.
2. Mean change from baseline in the hand grip strength score for the dominant hand by dynamometry at Week 76.
3. Mean change from baseline in the quadriceps strength score for the dominant leg by dynamometry at Week 76.
4. Mean change from baseline in the mTUG score at Week 76.

2.3. Safety Endpoints (Part A and Part B)

2.3.1. Part A (Sentinel Cohort)

2.3.2. Primary Endpoint

The primary endpoint for Part A of the study will be safety, as assessed by the incidence, type, and severity of treatment-emergent adverse events (TEAEs).

2.3.2.1. Secondary Endpoints

1. Incidence, type, and severity of treatment-emergent serious adverse events (TESAEs);
2. Incidence, type, and severity of TEAEs with onset within 24 hours from the start of any study medication administration;
3. Incidence of TEAEs leading to study medication or study discontinuation;
4. Clinically significant changes in standard laboratory parameters, vital signs, and ECGs;
5. AESIs:
 - a. Injection site reactions;
 - b. Systemic injection reactions (e.g., hypersensitivity, systemic inflammatory response);
 - c. Infection, including but not limited to, reactivation of latent herpes viruses such as EBV, CMV, human herpes virus (HHV), HSV-1 or -2, or VZV.

2.3.3. Part B (Double-Blind Safety and Efficacy Cohort)

1. Incidence, nature, and severity of TEAEs;
2. Incidence, nature, and severity of TESAEs;
3. Incidence, nature, and severity of TEAEs with onset within 24 hours from the start of any study medication administration;
4. Incidence of TEAEs leading to study medication or study discontinuation;
5. Changes in standard laboratory parameters, vital signs, and ECGs;
6. AESIs:
 - a. Injection site reactions;
 - b. Systemic injection reactions (e.g., hypersensitivity, systemic inflammatory response);
Infection, including but not limited to, reactivation of latent herpes viruses such as EBV, CMV, HHV, HSV-1 or -2, or VZV.

2.4. Pharmacokinetic, Pharmacodynamic and Immunogenicity Endpoints (Part B and Part C)

- Pharmacokinetic Endpoints: Serum concentration and PK parameters, when feasible, of ABC008.

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- PD recovery (Part C) as assessed by the time from End-of-Treatment (EOT)/Early Termination visit (ETV) to recovery of KLRG1+ cells.

There will be a separate Pharmacokinetic, Pharmacodynamic and Immunogenicity Analysis plan that will define the analysis and timepoints of these data. A separate report of these findings will be provided as an attachment to the Clinical Study Report.

2.5. Quality of Life Assessments

Quality of life assessments will be performed in the trial using the EuroQol 5-dimension, 5-level Quality-of-Life Questionnaire and Study 36-item Short Form Health Survey 2.

In addition, subjects at participating US sites may complete an optional Patient Exit Survey at their last visit. The Patient Exit Survey is designed to help identify subjects' perspectives on the effect of ABC008 on daily life.

3. ANALYSIS SETS

The following analysis sets will be used in Parts A, B and C:

Study Part	Analysis Set	Description
Parts A and B	Enrolled Analysis Set (ES)	Include all subjects screened and enrolled into the study. This set will be used to summarize subject disposition.
Parts A and B	Safety Analysis Set (SS)	Include all subjects who randomized and received at least one dose of study medication. The analyses using this set will be based upon the actual treatment assignment. All safety endpoints (e.g., AEs, laboratory results, vital signs, and ECG measurements) will be performed for the SS. In addition, demographics and baseline characteristics, protocol deviations, study drug exposure will be summarized using the SS.
Parts A and B	Full Analysis Set (FAS)	Include all subjects in the ES randomized to receive the study drug. The analyses using this set will be based upon the randomized treatment assignment. The FAS will be used to evaluate efficacy measures.
Parts A and B	Per Protocol Analysis Set (PPS)	Include all subjects in the FAS who completed the treatment period without an important protocol deviation that may impact efficacy assessment. The analyses using this set will be based upon the actual treatment assignment. Select efficacy assessments may be evaluated using the PPS.

Study Part	Analysis Set	Description
Parts A and B	Pharmacokinetic Analysis Set (PKS)	Include all subjects in the SS with at least one post-baseline time point with valid ABC008 concentration data. The analyses using this set will be based upon the actual treatment assignment.
Parts A and B	Pharmacodynamic Analysis Set (PDS)	Include all subjects in the SS with at least one post-baseline time point with valid PD assessments. The analyses using this set will be based upon the actual treatment assignment.
Part C	Pharmacodynamic Analysis Set (PDCS)	Include all subjects in the SS with at least one post-baseline time point with valid PD assessments. The analyses using this set will be based upon the actual treatment assignment.

4. GENERAL CONSIDERATIONS

Statistical programming and analyses will be performed using SAS® Version 9.4 or higher.

Any analysis not described in the SAP will be considered exploratory and will be documented in the clinical trial report as a post hoc analysis or a change to the planned analysis.

[Section 15](#) provides greater detail as to the specific outputs which are applicable for the data analysis. Listings with individual values will be provided for all data presented in the tables.

4.1. Summary of Part A, Part B and Part C

Unless otherwise specified, Part A and Part B will be summarized combined. Part C will be summarized separately.

4.2. Data Analysis Conventions

Summaries for continuous and ordinal variables will include the number of observations (n), arithmetic mean, standard deviation (SD), median, minimum, and maximum. Minima and maxima will be reported with the same precision as the raw values; means and medians will be presented to one additional decimal place than reported in the raw values. Standard deviations will be presented to two additional decimal places than reported in the raw values.

Summaries for discrete variables will include counts and percentages. All percentages will be rounded to one decimal place.

Safety summaries will be presented by the treatment group and overall, where appropriate, for each study visit.

Efficacy summaries will be presented by the treatment group.

All p-values will be rounded to 4 decimal places. P-values rounding to less than 0.0001 will be presented as “<0.0001”.

Listings will be sorted by treatment group, subject identifier, study visit or date of measurement and parameter, as applicable.

Dates will be printed as DDMMYYYY.

4.3. Treatment Comparisons

Between-treatment group comparisons are planned for:

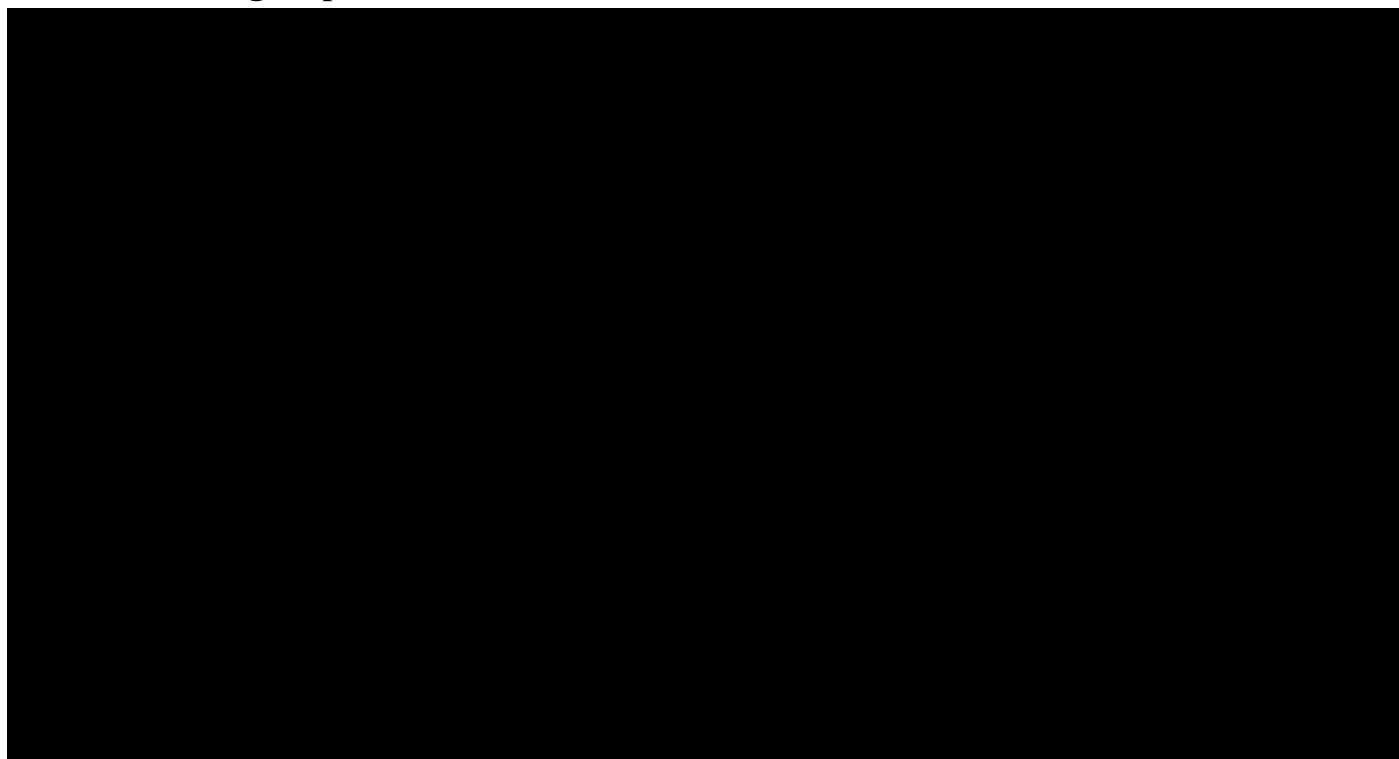
- ABC008 0.5 mg/kg vs Placebo.
- ABC008 2.0 mg/kg vs Placebo.

No between-treatment group comparisons are planned.

4.4. Baseline and Change from Baseline

Unless otherwise specified, Day 1 assessment value is considered as baseline. If Day 1 assessment is missing, baseline will be the last non-missing measurement observed prior to the first dose of study treatment. Change from baseline will be calculated as the data collected at post-randomization visits minus the baseline.

4.5. Subgroup Definitions



4.6. Calculated Variables

In general, the definitions presented below are applicable in the trial. The following unit conversion will be implemented unless otherwise specified:

- Months = Days/30.4375.
- Years = Days/365.25.

4.6.1. Duration (days)

Calculated as (Stop Date – Start Date + 1).

4.6.2. Day 1

For the purpose of the study, Day 1 is defined as the day of the first dose of trial treatment, and the day before is Day -1 (there is no Day 0).

4.6.3. Trial Day

- If the date of interest is on or after the date of the first dose, then Trial Day = (Date of interest – Date of first dose + 1).
- Otherwise, Trial Day = (Date of interest – Date of first dose).

4.6.4. Duration of Exposure

For each subject, the length of time from the first dose date of trial treatment to the date of last dose of trial treatment, and will be calculated as follows:

Date of last dose of trial treatment – Date of first dose of trial treatment + 1.

4.6.5. The End of the Trial

The end of the trial is defined as the date of the last subject's last visit in the trial.

4.7. Handling of Partial Dates

4.7.1. Partial Death Dates

It is recommended that the trial database be designed to mandate a complete death date. If there is a record for death, but the date is missing or is partial, it will be imputed based on the last contact date as follows:

- If the entire date is missing, the death date will be imputed as the day after the date of last contact.
- If the day or both day and month are missing, the death date will be derived as below:
1) impute partial dates to be 1st day of the month if day of death is missing, or January 1st if both day and month of death are missing, 2) compare the imputed dates with one day after the last known to be alive date, select the latest date. For example, if a subject with partial death date is known to be March 2020, and the last known to be alive date is March 16, 2020, then considering the rules of both 1) and 2), the death date will be imputed as March 17, 2020.

4.7.2. Partial Dates for Adverse Events and Medications

Partial or incomplete start/end dates for adverse events (AE) or medications will be imputed to help determine treatment-emergent adverse events as well as prior or concomitant medications.

For incomplete start dates for AEs or medications, the following imputation rules will be used:

- Missing day: Impute the 1st of the month unless month is same as month of first dose of trial treatment then impute using the day of first dose date
- Missing day and month: Impute 1st January unless year is the same as first dose date then impute using the first dose date
- Completely missing: Impute using first dose date unless the end date suggests it must have started prior to first dose, in which case impute the missing date with 01JAN of the same year as the first dose date.

When imputing a start date, ensure that the new imputed date is sensible, i.e., is prior to the end date of the AE or medication. If the imputed start date is after the end date, then the start date will be assumed equal to the end date.

For incomplete end dates for AEs or medications, the following imputation rules will be used:

- Missing day: Impute the last day of the month unless month and year are the same as the month and year of the last dose of trial treatment, then impute last dose date
- Missing day and month: Impute December 31 unless year is the same as last dose date then impute last dose date
- Completely missing: Need to look at whether the AE/medication is still ongoing before imputing a date and also when it started in relation to trial treatment. If the ongoing flag is not missing, then assume that AE is still present/medication is still being taken (i.e., do not impute the date). If the AE/medication is not ongoing and the start date is prior to first dose date, then impute the end date using 1st dose date. If it started on or after first dose date, then impute a date that is after the last dose date.

When imputing an end date, ensure that the new imputed date is sensible, i.e., is after the start date of the AE or medication. If the imputed end date is before the start date, then the end date will be assumed equal to the start date.

4.8. Scheduled and Unscheduled Visits

For by-visit summaries, only scheduled visits will be used in the analysis. There will be no visit windowing applicable to scheduled or unscheduled measurements. With the exception of the primary and key secondary efficacy endpoints, unscheduled measurements will only appear in data listings and shift tables where the worst post-baseline values are considered. For the primary and key secondary efficacy endpoints, if a subject performs an unscheduled visit and the nearest scheduled visit is missing, the unscheduled visit assessment would be reassigned, according to the protocol schedule of assessments, to the nearest scheduled visit that is missing.

4.9. Sort Order

In general, summary tables which are based on a hierarchical coding structure require a sort order. For medical history and adverse events tables (MedDRA coding), the sort order will be

alphabetical by System Organ Class then by descending frequency of preferred term using the first column.

For prior and concomitant medications, the sort order will be by descending frequency of the Preferred Name based on the WHO Drug Dictionary using the first column.

5. STATISTICAL METHODS

One-sided 0.025 significance levels and 95% confidence intervals will be used for all efficacy analyses unless an adjustment for multiplicity is specified.

5.1. Multiplicity Adjustment

A multiple testing procedure based on the graphical method ([Bretz et al., 2009](#)) will be applied to the primary and key secondary efficacy endpoints to control the overall Type I error rate at a one-sided 2.5% level.

The procedure will be applied to the null hypotheses of no treatment effect corresponding to the primary and key secondary efficacy endpoints, and the resulting hypothesis are defined in [Table 1](#)

Table 1: Null Hypothesis Based on the Primary and Key Secondary Efficacy Endpoints

Endpoint	Sequence 1 (0.5 mg/kg vs Placebo) One-sided significance level = 0.5%	Sequence 2 (2.0 mg/kg vs Placebo) One-sided significance level = 2%
Endpoint 1: IBMFRS	H_1	H_6
Endpoint 2: MMT-12	H_2	H_7
Endpoint 3: Grip strength for the dominant hand by dynamometry	H_3	H_8
Endpoint 4: Quadricep strength for the dominant leg by dynamometry	H_4	H_9
Endpoint 5: mTUG	H_5	H_{10}

As shown in [Table 1](#), the hypotheses will be grouped into two sequences corresponding to the two ABC008 doses. A one-sided 2.5% level will be split between the two dose-placebo comparisons as follows: a one-sided 0.5% level will be assigned to the comparison of 0.5 mg/kg vs placebo, and a one-sided 2% level will be assigned to the comparison of 2.0 mg/kg vs placebo. The resulting significance level for each sequence is shown in Table 1. Within each sequence, the hypotheses will be tested in a sequentially rejective manner at the sequence-specific significance level beginning with the hypothesis corresponding to Endpoint 1. For example, for Sequence 1, testing will begin with H_1 and proceed to the next hypothesis if all preceding hypotheses in the sequence have been rejected. Similarly, testing will begin with H_6 in Sequence 2 and proceed to the next hypothesis if all preceding hypotheses in the sequence have been rejected.

5.2. Missing Data Imputation

The primary and key secondary efficacy endpoints will be imputed as stated in [Section 11.1](#).

The following rules will be applied to address missing component (muscle-specific) scores for MMT-12:

- If $\leq 25\%$ of muscle-specific scores are missing, the total score will be calculated using the available muscles.
- If a muscle-specific score is missing for patient-related reasons, e.g., the patient can no longer perform the test, the score will be set to 0 before calculating the total score.
- If $> 25\%$ of muscle-specific scores are missing, the MMT total score will be set to missing.

Besides these imputation strategies, there will be no imputation of missing data other than for partial or missing dates where complete dates are required to flag data as treatment-emergent or concomitant with treatment. Imputation of partial/missing start and end dates for AEs and concomitant medications is described in [Section 4.7](#).

5.3. Sample Size

Approximately 231 subjects (79 subjects in each of the ABC008 arms and 73 subjects in the placebo arm) will be administered study medication in Parts A and B. This sample size provides overall power of at least 90% for the primary efficacy analysis at an overall one-sided 2.5% level if the true effect size at each ABC008 dose is 0.5448 for IBMFRS at 76 weeks. This effect size of 0.5448 is computed under the assumption of halting disease progression at 76 weeks. In addition, 15% of the subjects are expected to be lost to follow-up by the end of the 76-week treatment period.

A sample size of 79 subjects in each of the ABC008 arms and 73 subjects in the placebo arm provides marginal power levels (without accounting for the sequential testing process) shown in [Table 2](#) for each of the key secondary efficacy endpoints.

Table 2: Effect size and power calculation for the key secondary efficacy endpoints

Endpoint	Effect size	Power (%)
MMT-12	0.65	97.2
Grip strength for the dominant hand by dynamometry	0.59	94.0
Quadricep strength for the dominant leg by dynamometry	0.53	88.2
mTUG	0.44	74.1

6. SUBJECT DISPOSITION

Subject disposition and enrollment will be summarized by treatment group and total using the ES. The summaries will present the number and percentage of subjects who were

- Screened (total N only).
- Screen failed (total N only).
- Randomized.
- Randomized and did not receive study drug.
- Randomized and received study drug.
- Included in each analysis set.
- Discontinued treatment and by the primary reason for treatment discontinuation.
- Discontinued the study and by the primary reason for study discontinuation.

A listing of subject disposition and enrollment data will include the following information: treatment group, subject identifier, date of informed consent, date of randomization, analysis set, early discontinuation date (if applicable) and the primary reason for early discontinuation (if applicable).

7. PROTOCOL DEVIATIONS

Protocol deviations will be reviewed in a blinded fashion prior to the database lock to assess which subjects meet criteria for an important protocol deviation. A listing of important protocol deviations will include the following information: treatment group, subject identifier, protocol deviation.

8. DEMOGRAPHIC, CLINICAL AND OTHER BASELINE CHARACTERISTICS

Demographic, clinical and other baseline characteristics will be summarized by treatment group using the Safety Set. The following variables will be summarized:

- Age (years), gender and race/ethnicity, childbearing potential for females, height (cm), weight (kg) and BMI (cm/kg²) at baseline.
- Alcohol use, smoking.
- Age of symptom onset (years), age of diagnosis (years).
- Anti-cN-1A status, IBMFRS score at baseline, MMT-12 score at baseline, MMT-12 score at baseline, grip strength for the dominant hand, [REDACTED] quadriceps strength for the dominant leg, [REDACTED] mTUG score at baseline.
- [REDACTED] score at baseline, SF36-v2 PCS score at baseline, SF36-v2 MCS score at baseline, EQ-5D-5L score at baseline, [REDACTED] score at baseline, [REDACTED] score at baseline.

A listing of demographics and baseline characteristics will include the following information: treatment group, subject identifier and characteristic (unit).

9. MEDICAL HISTORY AND MEDICATIONS

9.1. Medical History

Medical history will be coded using the most current version of the Medical Dictionary for Regulatory Activities at the time of the study start (MedDRA Version 25.1 or higher).

Medical history will be summarized using the SS by MedDRA System Organ Class (SOC) and Preferred Term (PT). A subject will be counted once at the SOC level and once at each PT within the SOC level.

A listing of medical history data will include the following information: treatment group, subject identifier, SOC/PT/Verbatim term, start date, stop date, and status (resolved, ongoing with treatment, ongoing without treatment).

9.2. Disease History

A listing of diagnosis and disease history data will include the following information: treatment group, subject identifier.

9.3. Prior and Concomitant Medications

Concomitant medications are defined as all medications, including over the counter medications, vitamins, and herbal supplements, taken after the first study medication administration.

Prior medications are defined as any prescription or non-prescription drugs, including over the counter medications, vitamins, and herbal supplements, taken during the 12 weeks prior to the first study medication administration, but discontinued before dosing.

Prior and concomitant medications, including prior vaccinations, will be summarized using the SS. Concomitant medications will be coded using the latest version of the WHODrug Dictionary at the time of the study start – WhoDRUG Global B3 September 2022. All prior and concomitant medication will be classified using the Anatomical Therapeutic Chemical (ATC) classification codes level 4 and preferred drug names

Prior and concomitant medications will be summarized in separate tables by Preferred Name and treatment group. Subjects who receive multiple medications within a Preferred Name will be counted once in the summary tables for that Preferred Name.

A listing of prior and concomitant medications will include the following information: treatment group, subject identifier, prior/concomitant indicator (P or C), preferred name/reported name, start date, stop date, indication, adverse event treated, medical history treated, dose, total daily dose, dose unit, dose form, dose frequency, route and whether the medication is ongoing. A medication that is both prior and concomitant will be indicated by “P,C” in the listing.

In addition, a listing of prohibited medications will be created.

10. TREATMENT EXPOSURE AND COMPLIANCE

Trial treatment exposure, including the cumulative dose and duration of exposure, will be summarized. A summary of the following variables will be presented:

- Duration of Exposure (weeks on trial treatment): Number of days from the first to the last dose date, i.e., (last exposure date - first exposure date + 1)/7.

- Actual Cumulative Dose (mg): Sum of all administered doses (mg).
- Cumulative Planned Dose: Sum of all protocol-defined planned doses (mg) during the intended treatment duration period.
- Actual Dose Intensity (mg/week): $ADI = \text{Actual Cumulative Dose (mg)} / \text{Intended Treatment Duration (weeks)}$.
- Planned Dose Intensity (mg/week): $PDI = \text{Cumulative planned dose (mg)} / \text{Intended Treatment Duration (weeks)}$.
- Relative Dose Intensity (%): $RDI = 100 * ADI \text{ (mg/week)} / PDI \text{ (mg/week)}$.

Treatment compliance is defined as the ratio of the actual amount of medication taken by a subject to the expected amount of medication in the trial.

Treatment compliance will be summarized using standard descriptive statistics. In addition, the number and percentages of patients with compliance in the following categories will be presented: <80%, 80% to 105% and >105%.

Exposure and compliance data will also be presented in a data listing.

11. EFFICACY EVALUATIONS

The evaluation of the efficacy endpoints will be performed using the FAS and supportive analyses for the primary and key secondary efficacy endpoints will be performed using the PPS.

11.1. Primary Efficacy Endpoint

The primary efficacy endpoint is the change from baseline to Week 76 in the IBMFRS total score.

The primary analysis will be carried out using the following model: A mixed-effects repeated-measures model with fixed terms for treatment (ABC008 doses and placebo), baseline score, visit and visit by treatment interaction. Within-subject correlations will be modeled directly by specifying a covariance structure. By default, an unstructured covariance matrix for within-subject errors (common across the trial arms) will be fitted. If the model fails to converge, simpler covariance structures will be attempted within a pre-defined sequence (Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry) until convergence is achieved. The Kenwood-Rogers correction will be used to estimate denominator degrees of freedom if an unstructured covariance structure is specified and the robust sandwich estimator of variance will be used if a simpler covariance structure is chosen to avoid possible underestimation of the standard error due to covariance model misspecification.

Standard descriptive statistics, including the mean changes from baseline, mean percent changes from baseline, mean treatment differences, standard errors and 95% confidence intervals will be provided for each ABC008 dose at all post-baseline visits. In addition, a listing will be created to display the following information: treatment group, subject identifier, visit, absolute value of the IBMFRS total score and change from baseline.

11.1.1. Estimand Strategy

The primary estimand will be defined as a hybrid estimand, which combines several strategies for handling the intercurrent events defined below:

- Treatment condition: Administration of an ABC008 dose or placebo.
- Population: Randomized subjects with IBM.
- Endpoints: Change from baseline to Week 76 in the IBMFRS total score.
- Intercurrent events: Two types of ICEs are defined below.
- Population-level summary: Between treatment group difference for each ABC008 dose expressed in terms of the mean change.

The following ICEs will be defined for the primary estimand and analysis:

- ICE-1: Discontinuation of treatment due to lack of efficacy or death. This ICE will be handled using the “worst-case” hypothetical strategy implying that such subjects would have received no benefits from randomization until the end of the 76-week treatment period.
- ICE-2: Discontinuation of treatment due to an AE. This ICE will be handled using the “control-based” hypothetical strategy implying that such subjects would have switched to the control treatment (i.e., placebo) starting from the occurrence of ICE-2 to the end of the 76-week treatment period.

The main estimand will compare each ABC008 dose to placebo for the primary efficacy endpoint at the end of the corresponding treatment period. A hybrid strategy for handling ICEs during the treatment period will be used.

For subjects who have experienced any of the two ICEs, the outcome for the primary efficacy endpoint will be considered missing starting from the occurrence of each ICE (even if outcomes are collected following an ICE) and the missing outcomes will be imputed using appropriate imputation strategies:

- For ICE-1, the missing outcomes will be imputed using a Bayesian regression model fitted to the subset of subjects with 10% worst outcomes (based on the primary outcome at Week 76) within each treatment arm and an observed outcome at Week 76. Key demographic variables, endpoint-specific baseline scores and intermediate outcomes collected prior to the ICE will be included as covariates.
- For ICE-2, the missing outcomes will be imputed from a similar regression model fitted to the placebo arm alone with key demographic variables, endpoint-specific baseline scores and intermediate outcomes collected prior to the ICE included as covariates.

Missing data due to reasons unrelated to the two intercurrent events, e.g., intermittent missingness caused by skipped visits, will be imputed using a combination of Markov chain Monte-Carlo imputation to complete missingness to a monotone pattern followed by the same Bayesian regression model using monotone missingness as for ICE-1 and ICE-2 but fitted separately by treatment arm on all data based on the missingness at random assumption.

The final treatment effect estimates and p-values will be obtained using Rubin’s combination rules to produce a single inferential statement (mean treatment difference and p-value). A pre-defined seed value (123456) will be used for all calls to implement multiple imputations using PROC MI in SAS and the number of imputations will be set to 100.

11.1.2. Sensitivity Analyses

Sensitivity analyses based on control-based imputation and delta-adjusted imputation (tipping point) will be conducted. In all cases, a multiple imputation approach will be applied and imputation models will be based on the Bayesian regression model using monotone missingness. The estimated effects and associated standard errors from the individual completed data sets will be combined using Rubin's rules.

Specifically, two types of sensitivity analyses will be conducted for ICE-1 based on the model fitted to the subset of subjects with 10% worst outcomes (based on the primary outcome at Week 76):

- Control-based sensitivity analysis: The imputation model will be informed by the placebo arm alone.
- Delta-adjusted sensitivity analysis: The imputation model will be informed by the respective treatment arm as in the primary analysis but with a delta-adjusted tipping point strategy applied to the imputed outcomes.

Similarly, the following two types of sensitivity analyses will be conducted for ICE-2:

- Control-based sensitivity analysis: This analysis is very similar to the primary analysis but it will be applied only to placebo subjects who did not experience any ICEs.
- Delta-adjusted sensitivity analysis: This analysis will be based on a delta-adjusted strategy applied to the imputed outcomes based on the placebo arm alone.

The details are given in [Table 3](#) below. In addition, see the Appendix ([Section 14.1](#)) for more information on the sensitivity analyses. Examples of SAS code are provided in the Appendix ([Section 14.1](#)).

Table 3: Sensitivity Analyses for Two Types of Intercurrent Events

Analysis	ICE-1	ICE-2
Control-based imputation	Impute missing outcomes caused by ICE-1 for both treatment arms based on an imputation model informed by placebo subjects who did not have any of the ICEs using only the subset of data with 10% worst outcomes (based on the primary outcome at Week 76) from the placebo arm. The baseline data (key demographic variables, endpoint-specific baseline scores) and intermediate outcomes prior to the ICE will be used in the imputation model.	Impute missing outcomes caused by ICE-2 for both treatment arms based on an imputation model informed by placebo subjects with no ICEs. The baseline data (key demographic variables and endpoint-specific baseline scores) and intermediate outcomes prior to the ICE will be used in the imputation model. Note this is the same as the strategy for ICE-2 in the primary efficacy analysis except the imputation model will be trained only on subjects who did not experience any ICEs.
Delta-adjusted imputation	Similar to the strategy for ICE-1 in the primary analysis, i.e., imputations will be informed by the 10% worst outcomes within each treatment arm, but the primary efficacy outcome at Week 76 will be adjusted post-imputation by adding a predefined delta. Separate values of the delta parameter may be used in the ABC008 and placebo arms.	Same as the strategy for ICE-2 in the primary analysis but the primary efficacy outcome at Week 76 will be adjusted post-imputation by adding a predefined delta. Separate values of the delta parameter may be used in the ABC008 and placebo arms (although the same model fitted only to the placebo arm will be used for imputing data in all trial arms).

11.1.3. Supportive Analyses

The following supportive analyses will be performed for the primary endpoint:

- Based on the primary analysis model using the PPS.
- Based on the primary analysis model with additional covariates such as age, gender, [REDACTED] and [REDACTED] scores at baseline and anti-cN-1A status at screening.
- Based on the primary analysis model using the subset of subjects with the same rater at baseline and Week 76.

In addition, the following responder analyses will be performed for the primary endpoint:

- Percentage of responders defined as patients who experience no change or a positive [change](#) in the IBMFRS total score from baseline to Week 76.
- Percentage of responders defined as patients who experience a reduction of ≤ 1 point in the IBMFRS total score from baseline to Week 76.
- Percentage of responders defined as patients who experience a reduction of ≤ 2 points in the IBMFRS total score from baseline to Week 76.

The proportions of responders will be compared between each ABC008 dose and placebo using Fisher's exact test. A 95% confidence interval for each proportion will be computed using the Clopper-Pearson method. These analyses will be performed in the FAS using the primary imputation strategy defined in Section 11.1.1.

11.2. Key Secondary Efficacy Endpoints

The key secondary efficacy endpoints are defined in terms of changes from baseline to Week 76 in the MMT-12 total score, hand grip strength for the dominant hand by dynamometry, strength of quadriceps for the dominant leg by dynamometry and mTUG scores, respectively. The associated null hypotheses state that there is no difference between each ABC008 dose and placebo with regards to these endpoints.

The treatment effect on the key secondary efficacy endpoints will be evaluated using the primary analysis model in the FAS using the primary imputation strategy defined in [Section 11.1](#).

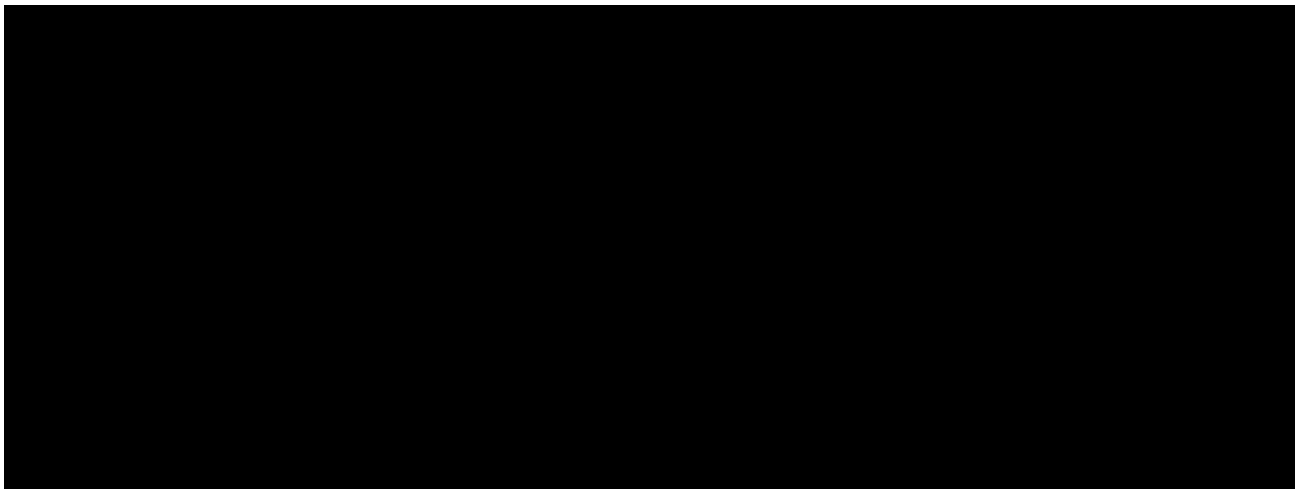
The estimand strategy and sensitivity analyses for the key secondary efficacy endpoints will be identical to those used in the primary analysis, see [Section 11.1.1](#) and [Section 11.1.2](#). In addition, supportive analyses will be performed using the primary analysis model in the PPS. A listing of efficacy data using the format specified in [Section 11.1](#) will be created.

The following supportive analyses will be performed for mTUG. The original results, measured in seconds, will be transformed as follows: 6 divided by the mTUG result, measured in meters per second. The transformed mTUG results will be analyzed using the primary analysis model. In addition, the proportion of patients who were unable to perform the mTUG at Week 76 will be computed in each trial arm. The proportions will be compared between each ABC008 dose and placebo using Fisher's exact test.

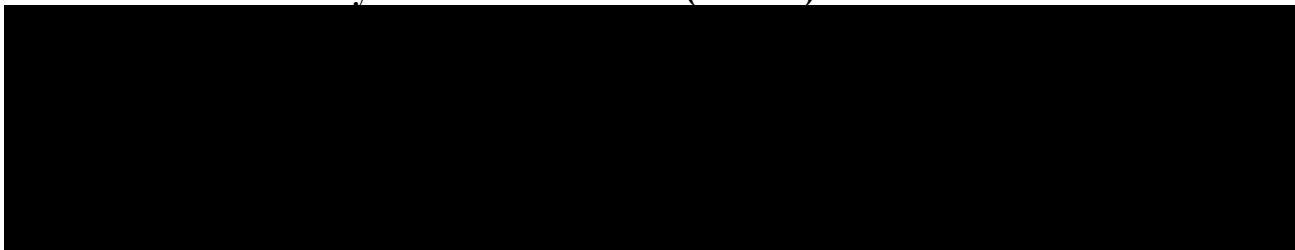
The following responder analysis will be performed for mTUG:

- Percentage of responders defined as patients who experience a positive reduction in the mTUG score from baseline to Week 76.

As in Section 11.1.3, the proportions of mTUG responders will be compared between each ABC008 dose and placebo using Fisher's exact test. A 95% confidence interval for each proportion will be computed using the Clopper-Pearson method. These analyses will be performed in the FAS using the primary imputation strategy.



11.4. Pharmacodynamic Assessments (Part C)

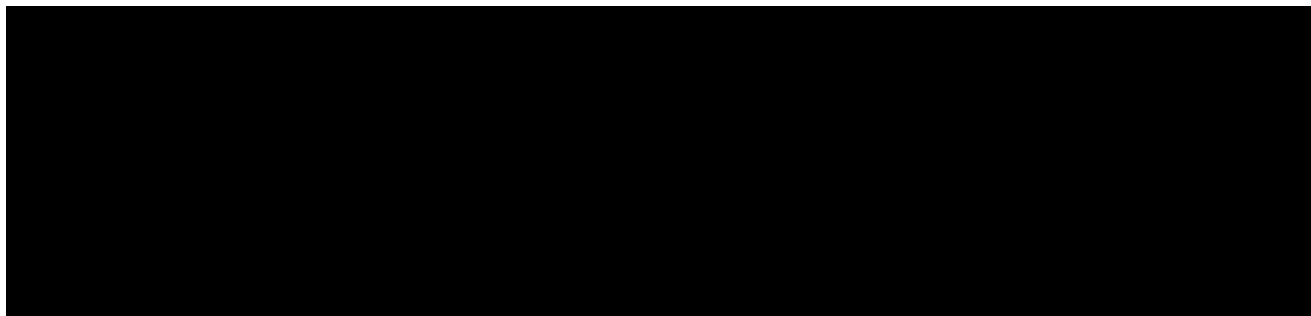


11.5. Quality of Life Analyses

The quality of life data will be summarized using the FAS.

Changes from baseline in the quality of life endpoints, i.e., the SF 36v2 physical component summary score, mental component summary score and individual domain scores as well as the EQ 5D 5L score, will be evaluated using the standard descriptive statistics by treatment group and visit. If relevant, analysis of covariance models may be applied to assess the significance of the treatment effect at the individual visits. A listing of quality of life data will be created.

A summary of the patient exit survey data will be presented. Counts and percentages of subjects will be computed for each question in each treatment group. A listing of survey data will be created.



12. SAFETY ANALYSIS

This section details the safety evaluations to be performed in the trial. All analyses in this section will be carried out using the SS.

12.1. Adverse Events

Adverse Events will be coded using the most current version of the Medical Dictionary for Regulatory Activities at the time of the study start (MedDRA Version 25.1).

For summaries of AEs by MedDRA System Organ Class (SOC) and Preferred Term (PT), a subject will be counted once at the SOC level and once at each PT within the SOC level. For summaries by SOC and PT, subjects may only contribute once to each PT and once to each SOC level.

Specific definitions for adverse events are as follows:

- An adverse event will be considered **related to trial treatment** if the category 'Related' is noted in the eCRF.
- An adverse event will be considered as **leading to discontinuation of trial treatment** if the option 'Treatment Withdrawn' is selected for the item 'Action taken with Trial Treatment' on the Adverse Events eCRF.
- An adverse event will be considered as **leading to death** if the Outcome on the Adverse Events eCRF is specified as 'Fatal'.

AESI include injection site reactions, systemic injection reactions, and infection.

Tabular summaries will be presented for Treatment-Emergent Adverse Events (TEAEs). TEAEs will be defined as AEs with an onset date on or after the date of first administration of study medication and before the date of last administration of study medication plus 30 days. Unless documented as a pre-existing condition, AEs with unknown start date will be counted as treatment-emergent. In addition, only post-dosing safety laboratory evaluations will be used for defining TEAEs.

TEAE summaries by SOC and PT will be presented by treatment group and total as follows:

- All TEAEs.
- TEAEs related to study drug as assessed by the investigator.
- TEAEs leading to study drug or study discontinuation.
- Treatment-emergent AESIs.
- Treatment-emergent AESIs related to study drug.
- Treatment-emergent AESIs leading to study drug or study discontinuation.

A listing of adverse events will include all AEs. This listing will display treatment group, subject identifier, SOC/PT/Verbatim term, TEAE (yes/no), serious (Yes/No), AESI (Yes/No), severity, start date (trial day) / stop date (trial day) / duration (days), relationship, action taken, outcome.

12.2. Deaths and Serious Adverse Events

Tabular summaries of Treatment-Emergent Serious Adverse Events by SOC and PT will be presented by treatment group and total as follows:

- Serious TEAEs.
- Serious TEAEs related to study drug.

A listing of all SAEs will be provided which contains the same information as the overall AE listing.

Information on fatal TEAEs will be summarized in tables by SOC and PT by treatment group and total as follows:

- TEAEs leading to death.
- Related TEAEs leading to death.

A listing of all AEs leading to death will be provided and will contain the same information as the overall AE listing.

Deaths will be summarized using the number and percentage of subjects by treatment group and total using the cause of death in the eCRF. Death information will also be provided in a listing and will contain the following information: treatment group, subject identifier, date of death and the primary cause of death (adverse event/progression of disease/other: specify).

12.3. Clinical Safety Laboratory Analysis

The evaluation of laboratory results will be performed for the following laboratory parameter categories (specific tests are defined in the protocol):

- Hematology.
- Clinical chemistry.
- Urinalysis.
- Complement levels.
- C-reactive protein.

For continuous laboratory parameters, values and changes from baseline will be summarized by treatment group and visit. For categorical parameters, the counts and frequencies will be presented by treatment group and visit.

Shifts tables for continuous laboratory parameters will also be presented by treatment group. The shift from the baseline value (low, normal, high) to each post-baseline visit value (low, normal, high) will be displayed.

Listings of laboratory parameters will be created for each laboratory parameter category. The listing will include treatment group, subject identifier, laboratory parameter (unit), date of sample, result and normal range. Values outside of the normal range will be flagged in the listing.

12.4. Physical Findings, Vital Signs, ECGs and Columbia Suicide Severity Rating Scale

12.4.1. Physical Examination

A data listing will include treatment group, subject identifier, body system examined, date of exam, examination result, and the details of any exam result deemed 'Abnormal, clinically significant'. All physical examination results for a subject will be displayed if the subject has at least one result deemed 'Abnormal, clinically significant'.

12.4.2. Vital Signs

The following vital signs will be considered for analysis: Systolic and diastolic blood pressure pulse, body temperature and respiration rate.

A summary table will display summary statistics for observed values and changes from baseline for each vital sign parameter by treatment group and visit. In addition, the number and percentage of subjects meeting each of the following criteria:

- Systolic Blood Pressure: <90 mmHg, >140 mmHg, >160 mmHg,
- Diastolic Blood Pressure: <50 mmHg, >90 mmHg, >100 mmHg,
- Pulse Rate: <60 bpm, >100 bpm,
- Body Weight: decrease of $\geq 7\%$ from baseline and increase of $\geq 7\%$ from baseline,
- Temperature: >38.0 °C, <36.0 °C,
- Respiratory rate: <12 breaths/min, > 20 breaths/min, at any post-baseline visit will be presented.

A supportive data listing will provide treatment group, subject identifier, vital sign parameter (unit), date of measurement, result and normal range. Values outside of the normal range will be flagged in the listing.

12.4.3. 12-Lead ECGs

The following 12-lead ECG parameters will be considered for analysis: Heart rate, PR interval, QRS interval, QT interval and QTcF (QTc interval corrected using Fridericia's criteria). The average of non-missing measurements from the triplicate 12-lead ECG assessments at each time point will be used in the analysis.

A summary table will display summary statistics of observed values and changes from baseline for each treatment arm, ECG parameter and visit. An additional summary table will display the number and percentage of subjects meeting criteria for abnormal QTc intervals at baseline and at any post-baseline visit, i.e., > 450 ms, > 480 ms and > 500 ms. A similar summary table will be created to display the number and percentage of subjects with the maximum change from baseline in QTc interval (≤ 30 ms, $> 30 - \leq 60$ ms, > 60 m).

The ECG evaluations with categorical results (normal; abnormal, not clinically significant; abnormal, clinically significant) will be summarized using a shift summary from baseline to the worst post-baseline evaluation. The worst-case evaluation from the triplicate 12-lead ECG assessments at each time point will be used in the analysis.

A data listing will include treatment group, subject identifier, date of measurement and qualitative and quantitative ECG evaluation (units). Abnormal QTc interval results based on the criteria defined above will be flagged in the listing.

12.4.4. Columbia Suicide Severity Rating Scale (C-SSRS)

A summary of the following scores at baseline and post-baseline visits will be created:

- Suicidal ideation score: The maximum suicidal ideation category (Categories 1-5).
- Suicidal ideation: A “yes” answer to any one of the five suicidal ideation questions (Categories 1-5).
- Suicidal behavior: A “yes” answer to any one of the five suicidal behavior questions (Categories 6-10).

Counts and percentages of subjects will be computed for each treatment arm, score and visit.

A data listing of the C-SSRS data will include treatment group, subject identifier, category (Categories 1-10), assessment date, response.

13. REFERENCES

Bretz F, Maurer W, Brannath W, Posch M. A graphical approach to sequentially rejective multiple test procedures. Stat Med. 2009;15;28(4):586-604.

14. APPENDIX

14.1. Examples of SAS Code

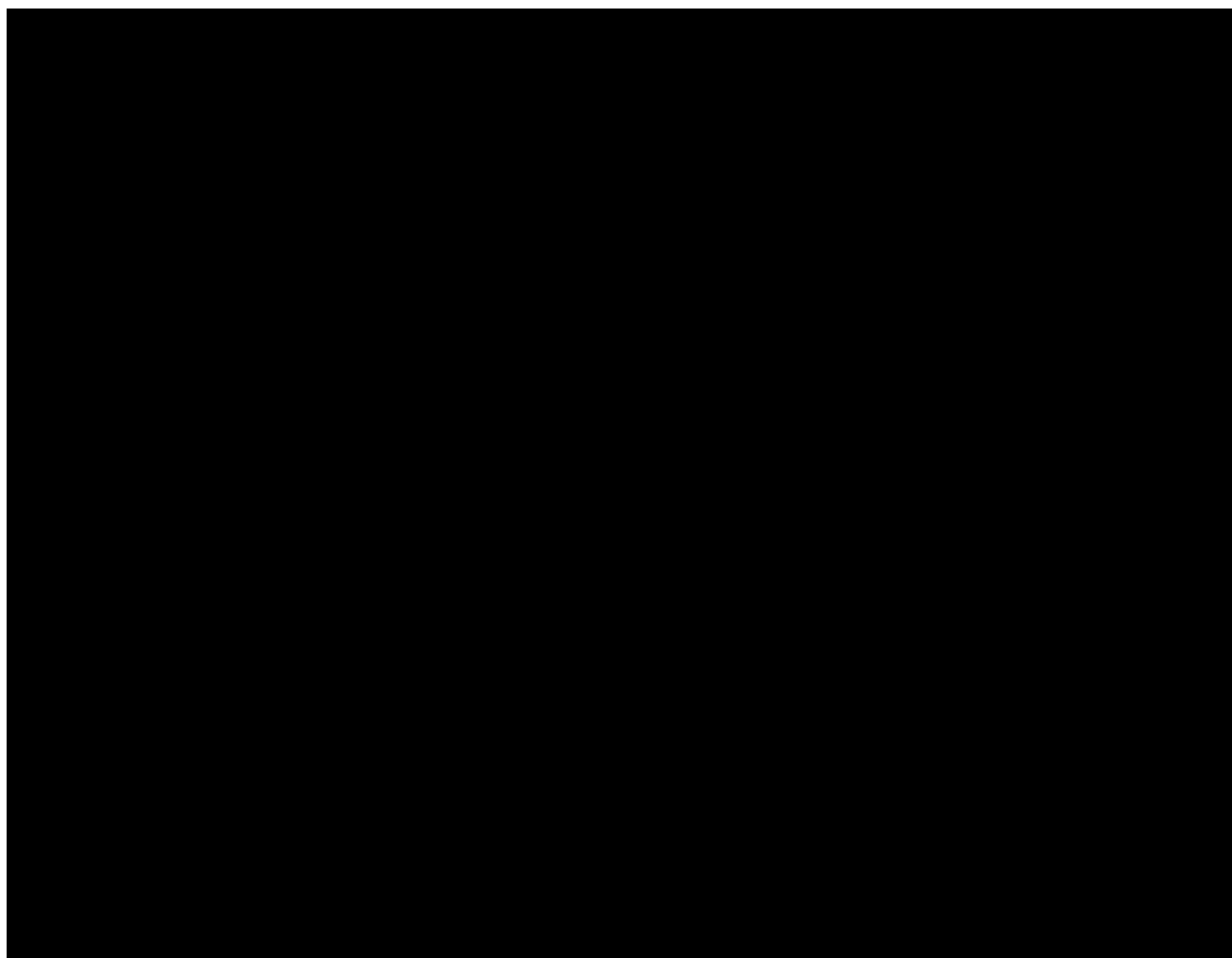
This section provides examples of SAS code for implementing multiple imputation-based analyses and other analyses defined in [Section 11](#).

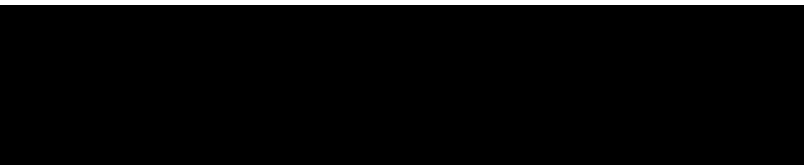
14.1.1. Imputing Intermittent Data Under MAR

Use MCMC to create $m=100$ imputed data sets completed to a monotone missingness pattern for the IBMFRS total score. Assume that the baseline score is coded as [REDACTED] scores for the intermediate visits are coded as [REDACTED] corresponding to Weeks 8, 16, 32, 48, 64 and finally Week 76 after randomization. The baseline covariates used in all imputation models are gender and age (other relevant covariates may be added as well).

We assume that ICEtype assuming values 0, 1 and 2 is a subject-level covariate indicating whether the subject had no ICEs, ICE-1 or ICE-2, respectively, that will be used in subsequent code examples. We assume that all observed values following the occurrence of ICE-1 or ICE-2 have been replaced with missing values.

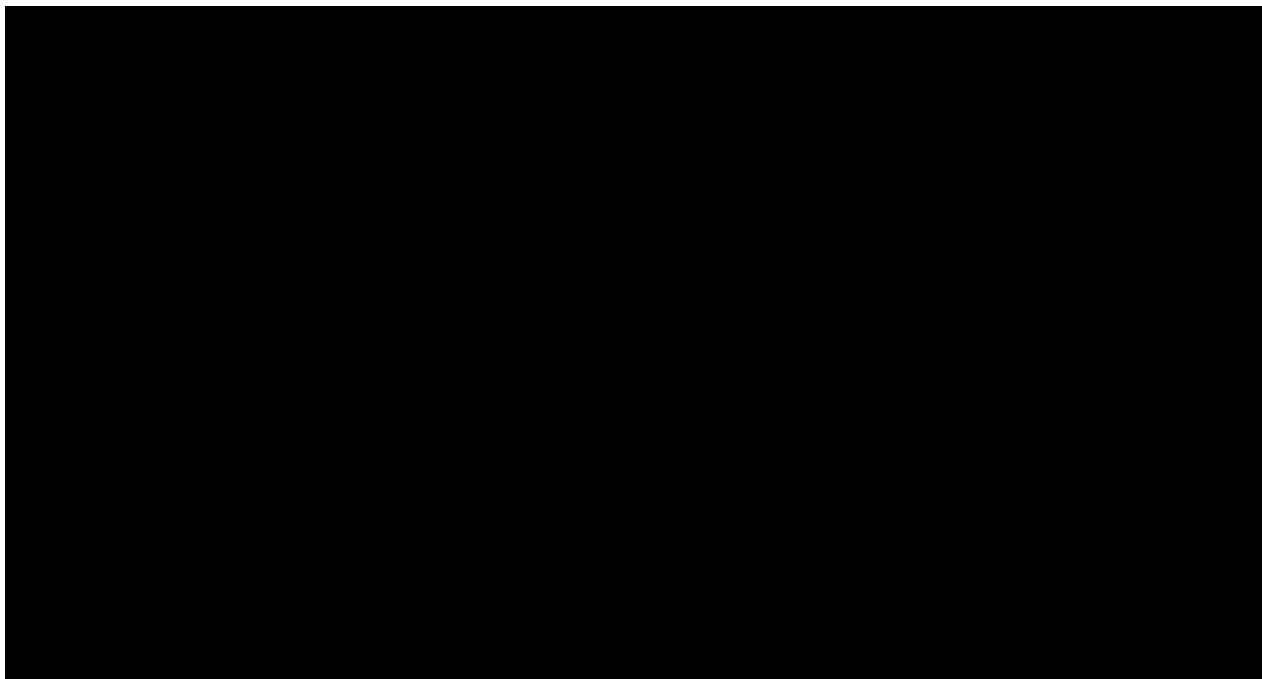
We also assume that the subject-level variable Worst10=0 and 1 assumes the value of 1 for subjects with no missing data at Week 76 who are in the subset of subjects with 10% worst outcomes in terms of the change from baseline in the IBMFRS total score at Week 76.



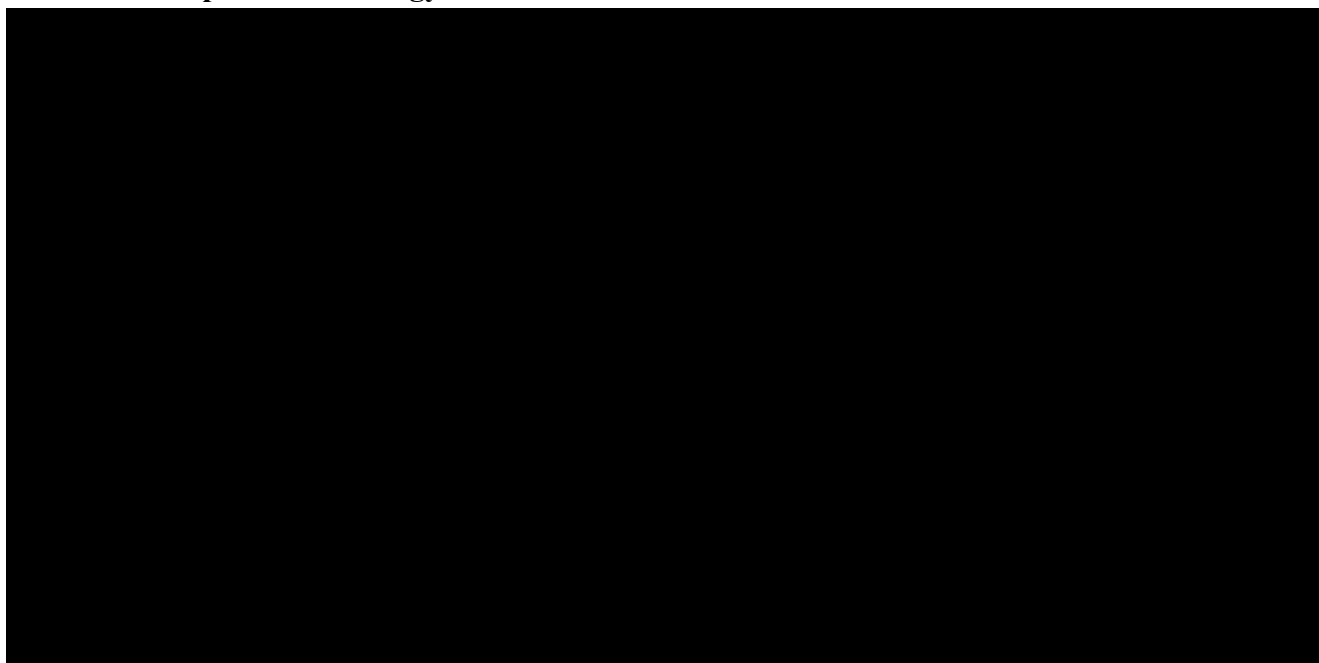


Note that the data set for imputing missing data caused by ICEs contains variable ImputeWeek 76 indicating whether the Week76 value needs to be imputed. It will be used in sensitivity analyses to determine whether the delta should be added for the tipping point sensitivity analysis to the imputed values at Week 76.

14.1.2. Imputation Strategy for ICE-1

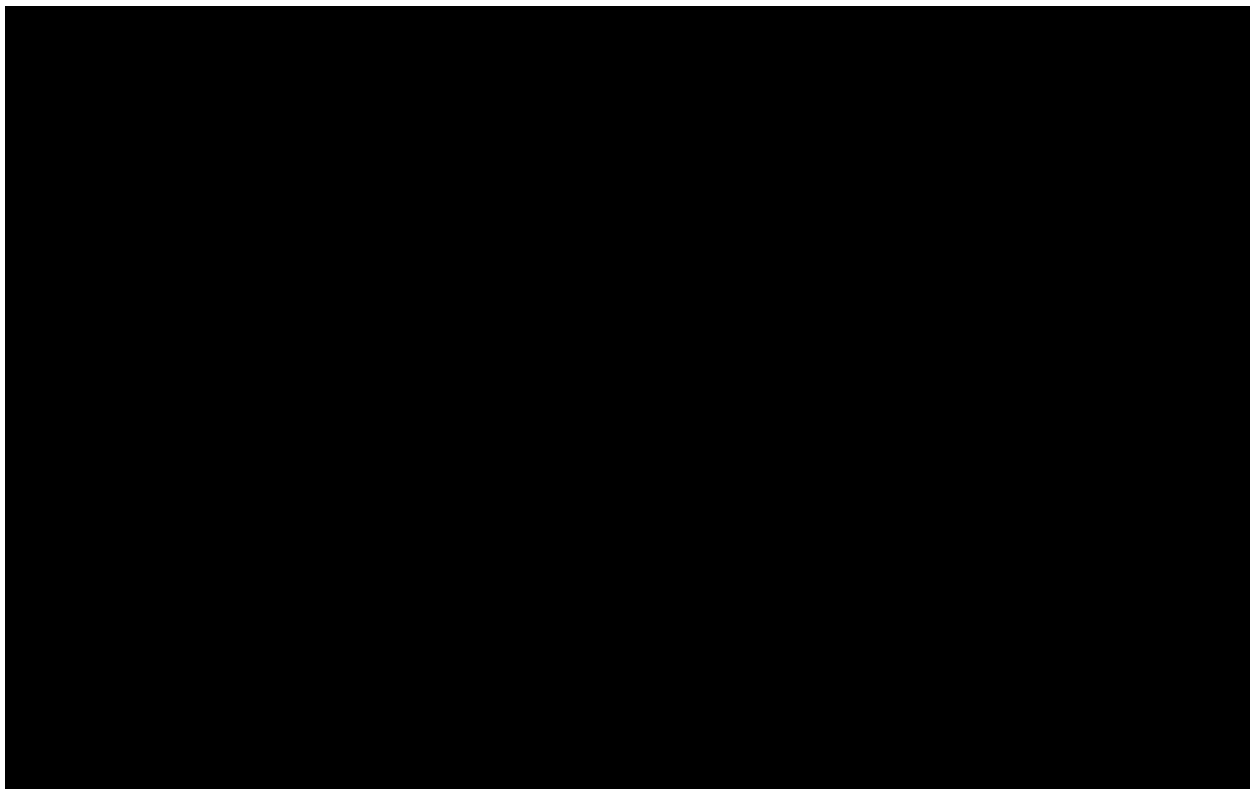


14.1.3. Imputation Strategy for ICE-2



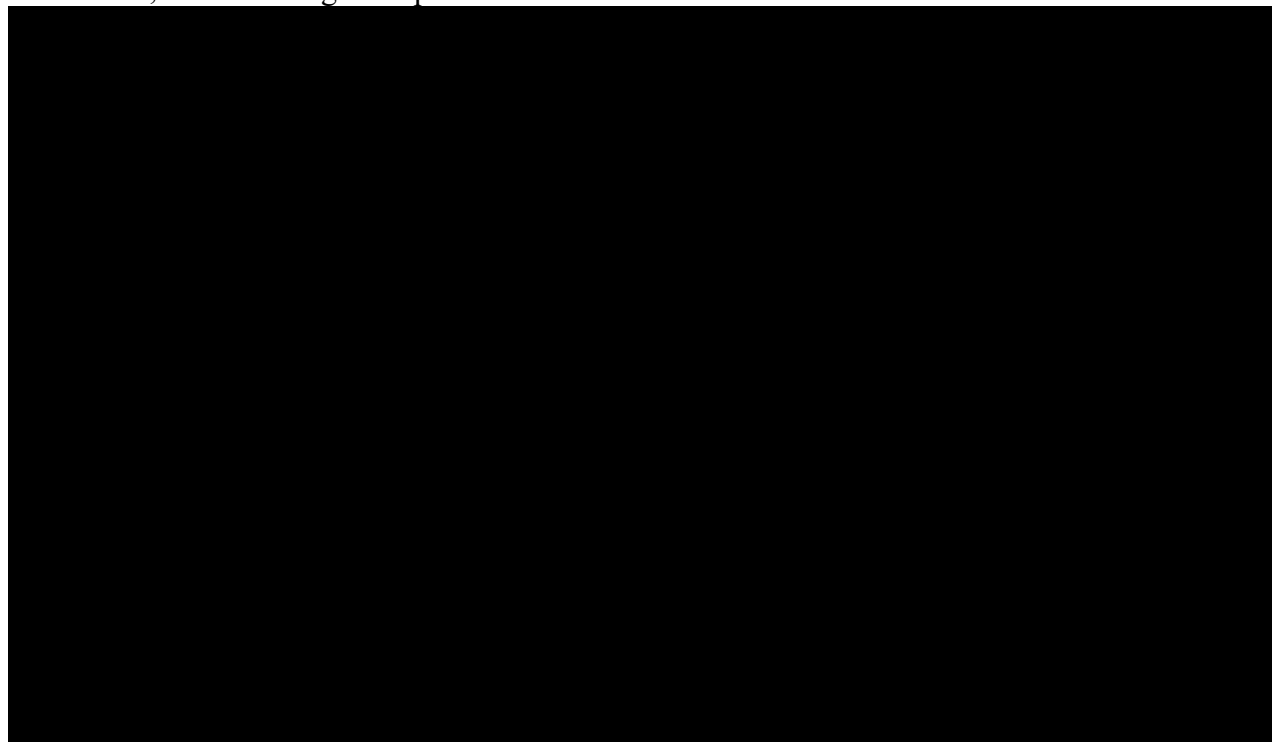


14.1.4. Combined Inference

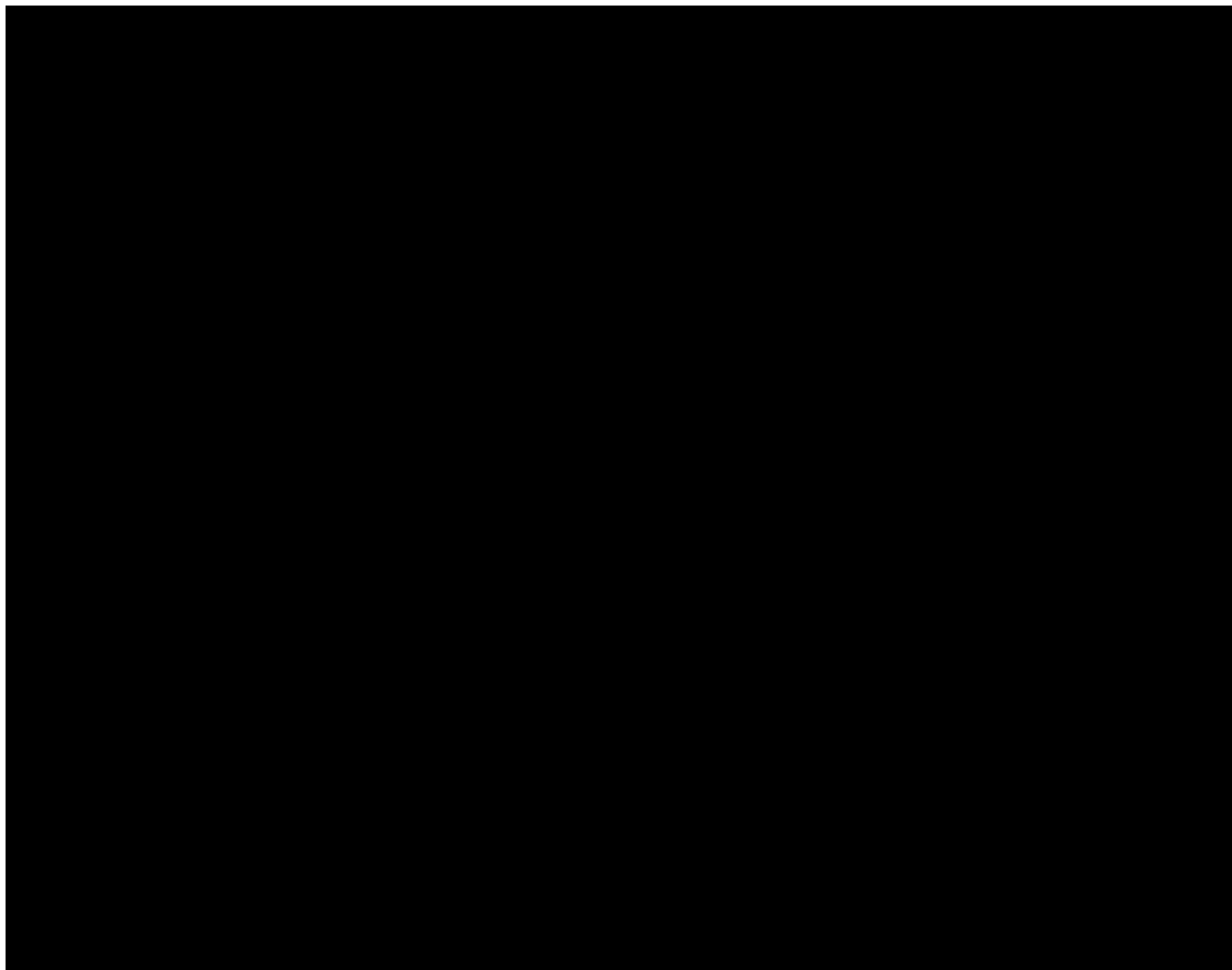


14.1.5. Sensitivity Analysis Using Control-Based Imputations

For ICE-1, the following example code will be used:

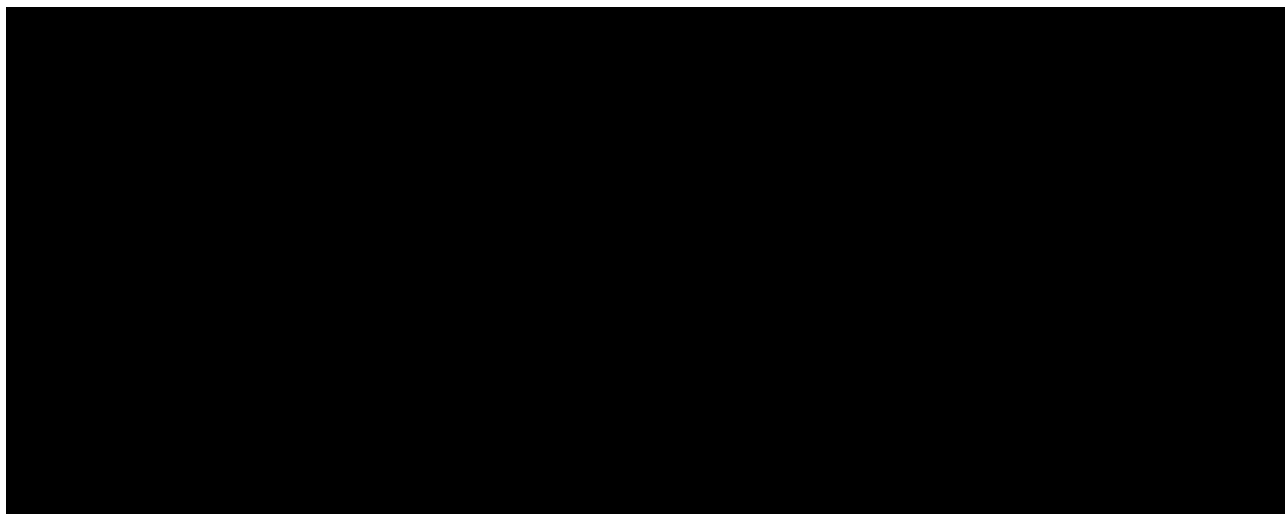


For ICE-2, the procedure is the same as for the primary analysis except that the imputation model will be trained on the placebo data for subjects with no ICEs:



14.1.6. Sensitivity Analysis Using Delta-Adjusted Imputations

For the delta-adjusted tipping point analysis, apply different delta0 and delta1 for placebo and ABC008 arms. Define a clinically plausible range of deltas and use a double do loop to generate multiple data sets for each combination of delta0 and delta1. Negative values of delta indicate worsening of outcomes because larger values on the IBMFRS rating scale are desirable functional outcomes. Run the primary analysis model on each imputed set for each combination of the deltas and combine the results for each combination using PROC MIANALYZE as shown previously. The final treatment effect estimates and p-values will be obtained using Rubin's combination rules to produce a single inferential statement (mean treatment difference and p-value). This will result in a two-dimensional set of delta-adjusted p-values. The tipping values of delta are those when the p-values become non-significant.



15. LISTS OF TABLES/GRAPHS/LISTINGS



Statistical Analysis Plan for Interventional Studies
TFL shells only

SAP Shell Version Number: v1.0
SAP Shell Date: 12-Jan-2026

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Protocol Number: ABC008-IBM-201

Protocol Title: A Phase II/III Randomized, Double-blind, Placebo-controlled, Multicenter Study to Determine the Efficacy and Safety of ABC008 in the Treatment of Subjects with Inclusion Body Myositis

Protocol Version and Date: Amendment 6, 01-Dec-2025

Syneos Health Project Code: 7040822

Authors



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V0.3	24-Jul-2025		Updated Version based on SAP v2.0
V0.4	07-Aug-2025		Updated Version based on SAP v2.0
V0.5	16-Oct-2025		Updated version to reflect dry run #1 outputs
V0.6	11-Nov-2025		Updated version to reflect SAP V2.0 and FDA feedback
V0.7	15-Dec-2025		Updated version to reflect updated SAP comments and included repeat lab outputs for conventional units. Made minor formatting changes and provided more details in the footnotes for clarification.
V1.0	12-Jan-2026		Final approved version

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Tables

Table 14.1.1.1
Summary of Subjects Enrollment and Disposition - Part A + B
Enrolled Analysis Set

	Placebo n (%)	ABC008 0.5mg/kg n (%)	ABC008 2.0mg/kg n (%)	Total n (%)
Subjects Screened				xx
Subjects Screen Failed				xx
Reasons for Screen Failures [a]				
Inclusion/exclusion criteria not met				xx (xx.x)
Adverse event				xx (xx.x)
Consent withdrawn				xx (xx.x)
Other				xx (xx.x)
Subjects Randomized	xx	xx	xx	xx
Randomized and did not receive study drug	xx	xx	xx	xx
Randomized and received study drug	xx	xx	xx	xx
Subjects in Full Analysis Set	xx	xx	xx	xx
Subjects in Safety Analysis Set	xx	xx	xx	xx
Subjects in Per-Protocol Set	xx	xx	xx	xx
Subjects in Pharmacodynamic Analysis Set	xx	xx	xx	xx
Subjects who Completed Treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects who Discontinued Treatment Early	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for Treatment Discontinuation [b]				
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Two Consecutive clinically significant increases in CMV or EBV viral load.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lack of efficacy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study Terminated By Sponsor or Regulatory Agency	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal by Subject (Other Than AE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow Up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Subjects who Completed Study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects who Discontinued Study Early	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for Study Discontinuation [b]				
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician Decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Two Consecutive Clinically Significant Increases In CMV or EBV Viral Load	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal by Subject	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study terminated by the Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects entered Part C [c]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects entered the open label study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: CMV = Cytomegalovirus, EBV = Epstein-Barr virus.

Note: Unless specified otherwise, the percentage is based on the number of subjects in the Safety Analysis Set.

Note: The Enrolled Analysis Set includes all subjects screened and enrolled into the study.

Note: The Full Analysis Set includes all subjects randomized to receive the study drug.

Note: The Safety Analysis Set includes all subjects who randomized and received at least one dose of study medication.

Note: The Per Protocol Set includes all subjects in the Full Analysis Set who completed the treatment period without an important protocol deviation that may impact efficacy assessment.

Note: The Pharmacodynamic Analysis Set includes all subjects in the Safety Analysis Set with at least one post-baseline time point with valid pharmacodynamic assessments.

[a] Percentages are based on subjects who screen failed.

[b] Percentages are based on subjects who discontinued treatment/study.

[c] Part C is a pharmacodynamic and safety follow-up to follow recovery of the depletion of KLRG1+ cells.

Cross Reference: Listing 16.2.1.1

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Table 14.1.1.2
Summary of Subjects Enrollment and Disposition - Part C
Enrolled Analysis Set

	Placebo n (%)	ABC008 0.5mg/kg n (%)	ABC008 2.0mg/kg n (%)	Total n (%)
Subjects who Enrolled to Part C [a]	xx	xx	xx	xx
Subjects in Pharmacodynamic Set	xx	xx	xx	xx
Subjects who Completed Part C	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Subjects who Discontinued from Part C [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for Study Discontinuation [b]				
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician Decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Two Consecutive Clinically Significant Increases In CMV or EBV Viral Load	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal by Subject	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Protocol Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study terminated by the Sponsor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: CMV = Cytomegalovirus, EBV = Epstein-Barr virus.

Note: Unless specified otherwise, the percentage is based on the number of subjects in the Safety Analysis Set.

Note: The Pharmacodynamic Analysis Set includes all subjects in the Safety Analysis Set with at least one post-baseline time point with valid pharmacodynamic assessments.

[a] Part C is a pharmacodynamic and safety follow-up to follow recovery of the depletion of KLRG1+ cells.

[b] Percentages are based on subjects who discontinued treatment/study.

Cross Reference: Listing 16.2.1.2

Source: ADSL

Program: xxxx.SAS

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Draft/Dry Run/Final Run

Table 14.1.1.3
Summary of Enrollment by Site - Part A + B
Full Analysis Set

Region	Country	Site	Placebo	ABC008	ABC008	Total
			(N=XX) n (%)	0.5mg/kg (N=XX) n (%)	2.0mg/kg (N=XX) n (%)	(N=XX) n (%)
North America	USA	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	CAN	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		...	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Australia	AUS	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		...	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Europe	BEL	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	DEU	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	FRA	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	GBR	xxxx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Cross Reference: Listing 16.2.1.1

Source: ADSL

Program: xxxx.SAS

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Table 14.1.1.4
Summary of Enrollment by Country - Part A + B
Full Analysis Set

Region	Country	Placebo	ABC008	ABC008	Total
		(N=XX) n (%)	0.5mg/kg (N=XX) n (%)	2.0mg/kg (N=XX) n (%)	(N=XX) n (%)
North America	USA	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	CAN	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Australia	AUS	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)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Europe	BEL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	DEU	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	FRA	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	GBR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Cross Reference: Listing 16.2.1.1

Source: ADSL

Program: xxxx.SAS

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Table 14.1.2.1
Important Protocol Deviations - Part A + B
Full Analysis Set

	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subjects with at least one important protocol deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Category xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being.

Note: A subject may have more than one protocol deviation under each category and counted once in that category.

Note: Percentages are based on subjects in the Full Analysis Set in each treatment group or Total.

Cross Reference: Listing 16.2.2.1

Source: ADDV

Program: xxxx.SAS

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Table 14.1.3.1.1
Subject Demographic and Baseline Characteristics - Part A + B
Safety Analysis Set

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Age (years) [a]				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Age category (years)				
18-44	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
45-64	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=65	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex, n (%)				
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Undifferentiated	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Childbearing potential for female, n (%) [a]				
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Congenitally or surgically sterile	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Post-menopausal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race, n (%) [b]				
American Indian or Alaska Native	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Multiple	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity, n (%)				
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Sponsor: Abcuro Inc; Protocol No.: ABC008-IBM-201

Abcuro Inc. Protocol ABC008-IBM-201**Page x of y****Draft/Dry Run/Final Run**

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Weight (kg)				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
BMI (kg/m ²)				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
BMI Category, n (%)				
<18.5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
18.5 -24.9	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
25-29.9	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=30	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Alcohol Use, n (%)				
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beer	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Wine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Distilled spirits	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Smoking, n (%)				
Has never smoked	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ex-smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: BMI = Body Mass Index, IMP = Investigational Medicinal Product, Max = Maximum, Min = Minimum, SD = Standard Deviation.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on subjects in the Safety Analysis Set, in each treatment group or Total, unless otherwise specified.

[a] Percentages are based on number of female subjects.

[b] Subjects could be counted under multiple races.

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Cross Reference: Listing 16.2.4.1

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Table 14.1.3.2.1
Baseline Disease Characteristics - Part A + B
Safety Analysis Set

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Age of symptom onset (years) [a]				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Age of diagnosis (years) [b]				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
ENMC Criterion met, n (%)				
Clinicopathologically defined IBM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Clinically defined IBM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Probably IBM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Aids used, n (%)				
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anti-cN-1A status, n (%)				
Positive/Borderline	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline IBMFRS				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline IBMFRS Category, n (%)				
<25	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=25	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
<29	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=29	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Baseline MMT-12				
n	xx	xx	xx	xx

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Sponsor: Abcuro Inc; Protocol No.: ABC008-IBM-201

Abcuro Inc. Protocol ABC008-IBM-201**Page x of y****Draft/Dry Run/Final Run**

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline MMT [REDACTED]				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline [REDACTED] Total score				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline SF36-v2 PCS score				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline SF36-v2 MCS score				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline EQ-5D-5L				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline Grip Strength, Dominant				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline Grip Strength, [REDACTED]				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx

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	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline Quadriceps Strength, Dominant				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline Quadriceps Strength, [REDACTED]				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline [REDACTED] n (%)				
1 = Not present	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 = Very mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 = Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 = Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5 = Moderately severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6 = Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7 = Extremely severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
<=3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline [REDACTED] n (%)				
1 = Normal, not at all ill	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 = Borderline ill	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 = Mildly ill	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4 = Moderately ill	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5 = Markedly ill	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6 = Severely ill	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7 = Among the most extremely ill patients	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
<=3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)

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Statistical Analysis Plan for Interventional Studies

Sponsor: Abcuro Inc; Protocol No.: ABC008-IBM-201

Abcuro Inc. Protocol ABC008-IBM-201**Page x of y****Draft/Dry Run/Final Run**

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline mTUG Score (seconds)				
n	xx	xx	xx	xx
Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median	xx.xx	xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Baseline mTUG Category, n (%)				
<= 20 seconds	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
> 20 seconds	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: ENMC = European Neuromuscular Centre, IBMFRS = Inclusion Body Myositis Functional Rating Scale, MMT = Manual Muscle Testing, [REDACTED] SF36-v2 = Study Short Form 36-item Health Survey Version [REDACTED] level Quality of Life, [REDACTED] of Disease Severity, [REDACTED] Min = Minimum, Max = Maximum, SD = Standard Deviation, FSH = Follicle Stimulating Hormone, IMP = Investigational Medicinal Product, mTUG = Modified Timed Up and Go.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on subjects in the Safety Analysis Set in each treatment group or Total, unless otherwise specified.

[a] Age in years is calculated using the symptom onset date and the birth date. If Month and/or day is missing, then January 1st is imputed for symptom onset date.

[b] Age in years is calculated using the diagnosis date and the birth date. If Month and/or day is missing, then January 1st is imputed for diagnosis date date.

Cross Reference: Listing 16.2.4.3

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Table 14.1.3.3.1
Summary of Medical History - Part A + B
Safety Analysis Set

System Organ Class Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subject with any Medical History	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				

Note: Medical History is coded using MedDRA Version xx.x. Subjects are counted only once for each system organ class and preferred term.

Note: Percentages are based on subjects in the Safety Analysis Set in each treatment group or Total.

Cross Reference: Listing 16.2.4.2

Source: ADMH

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Sort by descending order of overall frequency in Total column, by SOC and then PT, and then alphabetically within PT, if same frequency

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Table 14.1.3.4.1
Summary of Prior Medications - Part A + B
Safety Analysis Set

ATC Level 4 Term Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subject with any Prior Medications	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
ATC4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				

Note: Medications are coded using World Health Organization Drug Dictionary (WHO-DD) Global B3, Sept 2022. Prior medications are defined as any prescription or non prescription drugs, including over the counter medications, vitamins, and herbal supplements, taken during the 12 weeks prior to the first study medication administration, but discontinued before dosing. Subjects are counted only once for each medication class and each preferred term.

Note: Percentages are based on subjects in the Safety Analysis Set in each treatment group or Total.

Cross Reference: Listing 16.2.4.4

Source: ADCM

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Sort by descending frequency of ATC4 and then PT within a given ATC4, and then alphabetically if same PT in the Total column. Present 'Uncoded' as the last ATC4, and then all of the Uncoded terms underneath sorted by descending frequency in the Total column.

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Table 14.1.3.4.2
Summary of Concomitant Medications - Part A + B
Safety Analysis Set

ATC Level 4 Term Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subject with any Concomitant Medications	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
ATC4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				

Note: Medications are coded using World Health Organization Drug Dictionary (WHO-DD) Global B3, Sept 2022. Concomitant medications are defined as all medications, including over the counter medications, vitamins, and herbal supplements, taken after the first study medication administration. Subjects are counted only once for each ATC class and each preferred term.

Note: Percentages are based on subjects in the Safety Analysis Set in each treatment group or Total.

Cross Reference: Listing 16.2.4.4

Source; ADCM

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Sort by descending frequency of ATC4 and then PT within a given ATC4, and then alphabetically if same PT in the Total column. Present 'Uncoded' as the last ATC4, and then all of the Uncoded terms underneath sorted by descending frequency in the Total column.

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Table 14.1.5.1
Extent of Exposure and Compliance - Part A + B
Safety Analysis Set

	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Duration of Treatment(weeks)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Actual Cumulative Dose (mg)				
n	xx	xx	xx	xx
Mean (SD)	0	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median		xx.x	xx.x	xx.x
Min, Max		xx, xx	xx, xx	xx, xx
Cumulative Planned Dose(mg)				
n	xx	xx	xx	xx
Mean (SD)	0	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median		xx.x	xx.x	xx.x
Min, Max		xx, xx	xx, xx	xx, xx
Actual Dose Intensity (mg/week)				
n	xx	xx	xx	xx
Mean (SD)	0	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median		xx.x	xx.x	xx.x
Min, Max		xx, xx	xx, xx	xx, xx
Planned Dose Intensity (mg/week)				
n	xx	xx	xx	xx
Mean (SD)	0	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median		xx.x	xx.x	xx.x
Min, Max		xx, xx	xx, xx	xx, xx
Relative Dose Intensity (%):				
n	xx	xx	xx	xx
Mean (SD)	0	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
Median		xx.xx	xx.xx	xx.xx
Min, Max		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Number of Doses Missed				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)

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Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Overall Treatment Compliance (%)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Treatment Compliance Category				
< 80%	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
80% - 100%	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
> 100%	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: Min = Minimum, Max = Maximum, SD = Standard Deviation.

Note: Duration of treatment (days) = (Date of last dose - Date of first dose + 1)/7.

Note: Actual Cumulative Dose (mg) = Sum of all administered doses (mg).

Note: Cumulative Planned Dose = Sum of all protocol-defined planned doses (mg) during the intended treatment duration period.

Note: Actual Dose Intensity (mg/week) = Actual Cumulative Dose (mg)/Intended Treatment Duration (weeks).

Note: Planned Dose Intensity (mg/week) = Cumulative planned dose (mg)/Intended Treatment Duration (weeks).

Note: Relative Dose Intensity (%) = 100 * Actual Dose Intensity (mg/week)/Planned Dose Intensity (mg/week).

Note: Overall treatment compliance (%) = 100 * Total volume of injections received (mL)/Total volume of injections expected (mL).

Note: Percentages are based on subjects in the Safety Analysis Set in each treatment group or Total.

Cross Reference: Listing 16.2.5.1, 16.2.5.2

Source: ADEXSUM

Program: xxxx.SAS

Date cut-off: YYYY-MM-DD

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Table 14.2.1.1.1
Summary of Observed IBMFRS Total Score and Change from Baseline by Visit - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Actual value at Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Change from Baseline at Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Repeat for Week 16, 32, 48, 64, 76

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, Min = Minimum, Max = Maximum, SD = Standard Deviation, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at each visit and Baseline.

Cross Reference: Listing 16.2.6.1

Source: ADFT

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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Table 14.2.1.1.2
Primary Analysis: Change from Baseline in IBMFRS Total Score by Visit - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline at Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change	xx.x	xx.x	xx.x
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
LS Mean Difference of Change (vs Placebo)		xx.x	xx.x
95% CI		xx.x, xx.x	xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx

Repeat for Week 16, 32, 48, 64 and 76

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing IBMFRS scores were imputed using multiple imputation as described in SAP section 11.1.1.

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry > covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.1

Source: ADMI

Program: xxxx.SAS

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PROGRAMMING NOTE:**covariance structure order: TYPE = UN -> TOEP -> ARH(1)-> AR(1) -> CS**

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Table 14.2.1.1.3
Sensitivity Analysis 1: Change from Baseline in IBMFRS Total Score by Visit: Control-Based Imputation - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline at Week 8			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Min, Max	XX, XX	XX, XX	XX, XX
LS Mean of Change	XX.X	XX.X	XX.X
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LS Mean Difference of Change (vs Placebo)		XX.X	XX.X
95% CI		XX.X, XX.X	XX.X, XX.X
2-sided P value		0.xxxx	0.xxxx
Repeat for Week 16, 32, 48, 64 and 76			

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing IBMFRS scores were imputed using control-based multiple imputation as described in SAP section 11.1.2.

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.1

Source: ADMI

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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Table 14.2.1.1.4

Sensitivity Analysis 2: Change from Baseline in IBMFRS Total Score at Week 76: Delta-Adjusted Imputation - Part A + B
Full Analysis Set

<ABC008 0.5mg/kg/ ABC008 2.0mg/kg> vs Placebo

Additional Change Added to Placebo	Additional Change Added to ABC008 0.5mg/kg <ABC008 2.0mg/kg>							
	0.1	0.2	0.3	0.4	0.5	0.6	0.7	.
0.1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.2	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.4	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.5	x.xxx*	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.6	x.xxx*	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.7	x.xxx*	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
...	...	...	...	...	...	...	...	...

Abbreviations: IMP = Investigational Medicinal Product, ICE = intercurrent event, IBMFRS = Inclusion Body Myositis Functional Rating Scale.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Tipping point analysis is based on primary estimand, by gradually applied different change to Week 76 IBMFRS score impacted by ICE for placebo arm and ABC008 0.5mg/kg, ABC008 2.0mg/kg arm at until the testing significance not achieved (defined by *).

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.1

Source: ADMI

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

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Table 14.2.1.1.5

Supportive Analysis 1: Change from Baseline in IBMFRS Total Score by Visit (Primary Analysis) - Part A + B
Per Protocol Set

Repeat Table 14.2.1.1.2 for Per Protocol Set

PROGRAMMING NOTE:

Update SAP reference to section 11.1.2

Table 14.2.1.1.6

Supportive Analysis 2: Change from Baseline in IBMFRS Total Score by Visit (Primary Analysis) - Part A + B
Full Analysis Set

Repeat Table 14.2.1.1.2 using primary analysis model with additional covariates such as age, gender, [REDACTED] and [REDACTED] scores at baseline and anti cN 1A status at screening.

Footnote:

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing IBMFRS scores were imputed using multiple imputation as described in SAP section 11.1.2.

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry > covariance structure> covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score, age, gender, [REDACTED] and [REDACTED] scores at baseline and anti cN 1A status at screening as a covariate, and subject as the repeated random effect.

Table 14.2.1.1.7

Supportive Analysis 3: Change from Baseline in IBMFRS Total Score by Visit (Primary analysis) - Part A + B
Subjects with the Same Rater at Baseline and Week 76
Full Analysis Set

Repeat Table 14.2.1.1.2 for Subjects with the same rater at baseline and Week 76

PROGRAMMING NOTE:

Update SAP reference to section 11.1.2

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Table 14.2.1.1.8
Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Age - Observed Data - Part A + B
Full Analysis Set

Age	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
<=65			
Change from Baseline at Week 76			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change	xx.x	xx.x	xx.x
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
LS Mean Difference of Change (vs Placebo)		xx.x	xx.x
95% CI		xx.x, xx.x	xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx

>65

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.1

Source: ADFT

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

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Table 14.2.1.1.9

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Sex - Observed Data - Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.8 by Sex (Male vs Female)

Table 14.2.1.1.10

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Race - Observed Data - Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.8 by Race (White vs Non-white)

Table 14.2.1.1.11

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Anti-cN1A Status at Screening (Positive/Borderline versus Negative) - Observed Data - Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.8 by Anti-cN1A status at screening (positive/borderline versus negative).

Table 14.2.1.1.12

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Duration of Disease - Observed Data - Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.8 Duration of disease (< 8 years versus >= 8 years).

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Table 14.2.1.1.13

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Baseline IBMFRS Total Score Category - Observed Data - Part A + B
Full Analysis Set

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
IBMFRS Total Score Category			
< 25			
Change from Baseline at Week 76			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change			
95% CI	xx.x xx.x, xx.x	xx.x xx.x, xx.x	xx.x xx.x, xx.x
LS Mean Difference of Change (vs Placebo)			
95% CI		xx.x xx.x, xx.x	xx.x xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx
>= 25			
< 29			
>= 29			

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure for IBMFRS Total score Category='< 20' group, unstructured covariance structure for IBMFRS Total score Category='>=20' group, unstructured covariance structure for IBMFRS Total score Category='< 25' group and unstructured covariance structure for IBMFRS Total score Category='>=25' group, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.1

Source: ADFT

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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Programming note:

Repeat Table 14.2.1.1.8 for by baseline IBMFRS Total score Category (< 25 vs. ≥ 25 and < 29 vs. ≥ 29)

Table 14.2.1.1.14

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Change from Screening to Baseline - Observed Data -
Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.8 by IBMFRS score Change from Screening to Baseline (≥ 2 in either direction versus < 2 in either direction).

Table 14.2.1.1.15

Primary Analysis: Change from Baseline to Week 76 in IBMFRS Total Score by Baseline mTUG Score - Observed Data - Part A + B
Full Analysis Set

Repeat Table 14.2.1.1.8 by Baseline mTUG total score (≤ 20 seconds versus > 20 seconds).

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Table 14.2.1.1.16

Supportive Analysis: Percentage of Responders who Experience Reduction in the IBMFRS Total Score from Baseline to Week 76 - Part A
+ B
Full Analysis Set

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
IBMFRS Total Score from Baseline to Week 76			
n	xx	xx	xx
No change or a positive change m (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
1-sided P value		0.xxxx	0.xxxx
A reduction of <= 1 point m (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
1-sided P value		0.xxxx	0.xxxx
A reduction of <= 2 points m (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
1-sided P value		0.xxxx	0.xxxx

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, IMP = Investigational Medicinal Product, CI = Confidence interval.

Note: n is total number of subjects who have an assessment visit at baseline and Week 76.

Note: Count, percentage and 95% CI using the Clopper-Pearson method were computed using observed data. The 1-sided P-value was calculated using the Fisher's exact test where missing IBMFRS scores were imputed using multiple imputation as described in SAP section 11.1.1. The exact p-values were converted to Z-statistics via an inverse normal cumulative distribution function and Rubin's rules were applied to the resulting Z-statistics across the multiply-imputed datasets to obtain an overall p-value comparing each treatment group to Placebo.

Cross Reference: Listing 16.2.6.1

Source: ADFT, ADMI

Program: xxxx.SAS

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Table 14.2.2.1.1
MMT-12 Score and Change from Baseline by Visit - Observed Data - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Week 8 Change from Baseline			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Repeat for Week 16, 32, 64, 76			

Abbreviations: MMT = Manual Muscle Testing, Min = Minimum, Max = Maximum, SD = Standard Deviation, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Cross Reference: Listing 16.2.6.2

Source: ADMK

Program: xxxx.SAS

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Table 14.2.2.1.2
Primary Analysis: Mean Change from Baseline in MMT-12 Score by Visit - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline at Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change	xx.x	xx.x	xx.x
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
LS Mean Difference of Change (vs Placebo)		xx.x	xx.x
95% CI		xx.x, xx.x	xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx
Repeat for Week 16, 32, 64 and 76			

Abbreviations: MMT = Manual Muscle Testing, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing MMT-12 score were imputed using multiple imputation as described in SAP section 11.1.1.

Note: The change from Baseline in MMT-12 is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.2

Source: ADMI

Program: xxxx.SAS

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Table 14.2.2.1.3

Sensitivity Analysis 1: Mean Change from Baseline in MMT-12 Score by Visit: Control-Based imputation - Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.3 for in MMT-12

Table 14.2.2.1.4

Sensitivity Analysis 2: Mean Change from Baseline in MMT-12 Score by Visit: Delta-Adjusted imputation - Part A + B

Full Analysis Set

Repeat Table 14.2.1.1.4 for in MMT-12

Table 14.2.2.1.5

Supportive Analysis: Mean Change from Baseline in MMT-12 Score by Visit (Primary Analysis) - Part A + B

Per Protocol Set

Repeat Table 14.2.2.1.2 using Per Protocol Set

PROGRAMMING NOTE:

Update SAP reference to section 11.1.2

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Table 14.2.2.2.1
Dynamometry Grip Strength and Change from Baseline by Visit - Observed Data - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Dominant Hand [REDACTED]			
Day 1 (Baseline)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Week 8 Change from Baseline			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Repeat for Week 16, 32, 64, 76			

Abbreviations: Min = Minimum, Max = Maximum, SD = Standard Deviation, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Cross Reference: Listing 16.2.6.3

Source: ADMK

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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PROGRAMMING NOTE:

Produce table for dominant hand first, followed by [REDACTED]

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Table 14.2.2.2.2a

Primary Analysis: Mean Change from Baseline in Dynamometry Grip Strength for the Dominant Hand by Visit - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline at Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change	xx.x	xx.x	xx.x
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
LS Mean Difference of Change (vs Placebo)		xx.x	xx.x
95% CI		xx.x, xx.x	xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx

Repeat for Week 16, 32, 64 and 76

Abbreviations: Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing dynamometry grip strength were imputed using multiple imputation as described in SAP section 11.1.1.

Note: The change from Baseline in dynamometry grip strength is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

PROGRAMMING NOTE:Produce table for dominant hand only.

Cross Reference: Listing 16.2.6.3

Source: ADMI

Program: xxxx.SAS

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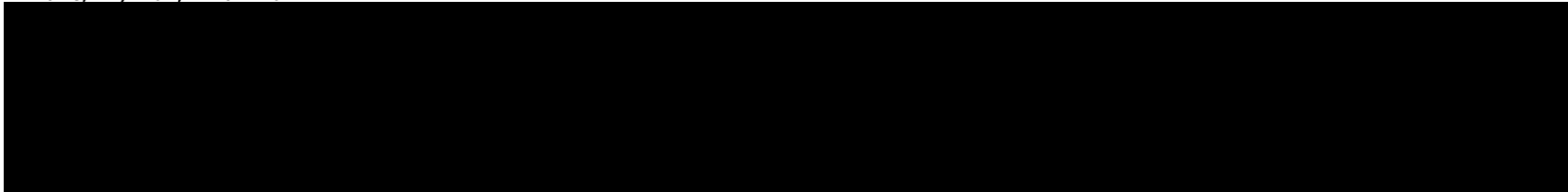
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Table 14.2.2.2.3

Sensitivity Analysis 1: Mean Change from Baseline in Dynamometry Grip Strength for the Dominant Hand by Visit: Control-Based Imputation - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline at Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change	xx.x	xx.x	xx.x
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
LS Mean Difference of Change (vs Placebo)		xx.x	xx.x
95% CI		xx.x, xx.x	xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx

Repeat for Week 16, 32, 48, 64 and 76

Abbreviations: Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistical Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing dynamometry grip strength scores were imputed using control-based multiple imputation as described in SAP section 11.1.2.

Note: The change from Baseline in dynamometry grip strength is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.3

Source: ADMI

Program: xxxx.SAS

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PROGRAMMING NOTE:Produce table for dominant hand only.

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Table 14.2.2.2.4

Sensitivity Analysis 2: Mean Change from Baseline in Dynamometry Grip Strength for the Dominant Hand by Visit: Delta-Adjusted
Imputation - Part A + B
Full Analysis Set

<ABC008 0.5mg/kg ABC008 2.0mg/kg> vs Placebo

Additional Change Added to Placebo	Additional Change Added to ABC008 0.5mg/kg <ABC008 2.0mg/kg>							
	0.1	0.2	0.3	0.4	0.5	0.6	0.7	.
0.1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.2	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.4	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.5	x.xxx*	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.6	x.xxx*	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
0.7	x.xxx*	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
...	...	...	...	...	...	...	...	...

Abbreviations: IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Tipping point analysis is based on primary estimand, imputed by gradually increasing the different Delta adjusted change to placebo arm and ABC008 0.5mg/kg, ABC008 2.0mg/kg until the testing significance not achieved (defined by *).

Cross Reference: Listing 16.2.6.3

Source: ADMI

Program: xxxx.SAS

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PROGRAMMING NOTE:Produce table for dominant hand only.

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Table 14.2.2.2.5

Supportive Analysis: Mean Change from Baseline in Dynamometry Grip Strength for the Dominant Hand by Visit (Primary Analysis) -
Part A + B
Per Protocol Set

Repeat Table 14.2.2.2a for Per Protocol Set

PROGRAMMING NOTE:

Update SAP reference to section 11.1.3
Keep both dominant hand

Table 14.2.2.3.1

Dynamometry Quadriceps Strength and Change from Baseline by Visit - Observed Data - Part A + B
Full Analysis Set

Repeat Table 14.2.2.2.1 for Dynamometry Quadriceps Strength

PROGRAMMING NOTE:

Produce table for dominant leg first, followed by [REDACTED] Update by-line to indicate 'Dominant Leg/[REDACTED]
instead of 'Dominant Hand/[REDACTED]
Update 'dynamometry grip strength' to 'dynamometry quadriceps strength'.

Cross Reference: Listing 16.2.6.4

Source: ADMK

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Table 14.2.2.3.2a

Primary Analysis: Mean Change from Baseline in Dynamometry Quadriceps Strength for the Dominant Leg by Visit - Part A + B
Full Analysis Set

Repeat Table 14.2.2.2a for Dynamometry Quadriceps Strength

PROGRAMMING NOTE:

Produce table for dominant leg only
Update 'dynamometry grip strength' to 'dynamometry quadriceps strength'.

Cross Reference: Listing 16.2.6.4

Source: ADMI

Program: xxxx.SAS

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Table 14.2.2.3.3

Sensitivity Analysis 1: Mean Change from Baseline in Dynamometry Quadriceps Strength for the Dominant Leg by Visit: Control-Based
Imputation- Part A + B
Full Analysis Set

Repeat Table 14.2.2.2.3 for Dynamometry Quadriceps Strength

PROGRAMMING NOTE:

Produce table for dominant leg only

Update 'dynamometry grip strength' to 'dynamometry quadriceps strength'.

Cross Reference: Listing 16.2.6.4

Source: ADMI

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Table 14.2.2.3.4

Sensitivity Analysis 2: Mean Change from Baseline in Dynamometry Quadriceps Strength for the Dominant Leg by Visit: Delta-Adjusted
Imputation - Part A + B
Full Analysis Set

Repeat Table 14.2.2.2.4 for Dynamometry Quadriceps Strength

PROGRAMMING NOTE:

Produce table for dominant leg only.

Update 'dynamometry grip strength' to 'dynamometry quadriceps strength'.

Cross Reference: Listing 16.2.6.4

Source: ADMI

Program: xxxx.SAS

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Table 14.2.2.3.5

Supportive Analysis: Mean Change from Baseline in Dynamometry Quadriceps Strength for the Dominant Leg by Visit (Primary Analysis)

- Part A + B

Per Protocol Set

Repeat Table 14.2.2.3.2 for Per Protocol Set

PROGRAMMING NOTE:

Produce table for dominant leg only.

Update 'dynamometry grip strength' to 'dynamometry quadriceps strength'.

Update SAP reference to section 11.1.2

Cross Reference: Listing 16.2.6.4

Source: ADMI

Program: xxxx.SAS

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Table 14.2.2.4.1

mTUG and Change from Baseline by Visit - Observed Data - Part A + B
Full Analysis Set

Repeat Table 14.2.2.1.1 for mTUG

Cross Reference: Listing 16.2.6.5

Source: ADFT

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

Note: All results recorded as 300 seconds will be set to missing.

Table 14.2.2.4.2

Primary Analysis: Mean Change from Baseline in mTUG by Visit - Part A + B
Full Analysis Set

Repeat Table 14.2.2.1.2 for mTUG

Abbreviations: mTUG = Modified Timed Up and Go, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistics Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing mTUG scores were imputed using multiple imputation as described in SAP section 11.1.1.

Note: The change from Baseline in mTUG is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry > covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.5

Source: ADMI

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT-12' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

This document is confidential.

Table 14.2.2.4.3

Sensitivity Analysis 1: Mean Change from Baseline in mTUG by Visit: Control-Based Imputation - Part A + B
Full Analysis Set

Repeat Table 14.2.2.1.3 for mTUG

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT-12' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

Table 14.2.2.4.4

Sensitivity Analysis 2: Mean Change from Baseline in mTUG by Visit: Delta-Adjusted Imputation - Part A + B
Full Analysis Set

Repeat Table 14.2.2.1.4 for mTUG

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT-12' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

Table 14.2.2.4.5

Supportive Analysis: Mean Change from Baseline in mTUG by Visit (Primary Analysis) - Part A + B
Per Protocol Set

Repeat Table 14.2.2.4.2 for Per Protocol Set

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT-12' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

Update SAP reference to section 11.1.2

Table 14.2.2.4.6

Primary Analysis: mTUG Change from Baseline to Week 76 for Subjects with CN1a Ab+ - Part A + B
Full Analysis Set

Repeat Table 14.2.2.4.2 for Subjects with CN1a Ab+

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT-12' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

This document is confidential.

Table 14.2.2.4.7

Supportive Analysis: Mean Change from Baseline in Transformed mTUG by Visit - Part A + B

Full Analysis Set

Repeat Table 14.2.2.4.2 for transformed mTUG

Abbreviations: mTUG = Modified Timed Up and Go, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product, SAP = Statistics Analysis Plan.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Missing mTUG scores were imputed using multiple imputation for primary estimand as described in SAP section 11.1.1.

Note: Transformed mTUG = 6 divided by the mTUG result measured in meters per second.

Note: The change from Baseline in mTUG is analyzed using a mixed model repeated measures (MMRM) with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry > covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Listing 16.2.6.5

Source: ADMI

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Update in footnotes to replace 'MMT-12' to 'mTUG' and 'MMT = Manual Muscle Testing' to 'mTUG = Modified Timed Up and Go Test'.

Update SAP reference to section 11.1.2

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Table 14.2.2.4.8
Proportion of Participant Failed in mTUG Test by Visit - Observed Data - Part A + B
Full Analysis Set

Visit	mTUG Test	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Baseline (Day 1)	Evaluable population, n	xx	xx	xx
	Failed, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	P value vs Placebo	x.xxxx	x.xxxx	x.xxxx

Repeat for week 8, 16,
32, 64, 76

Abbreviations: mTUG = Modified Timed Up and Go, CI = Confidence Interval, NE = Not Estimatable.

Note: The p value is based on the Fisher's exact test.

Note: All results recorded as 300 seconds will be set to missing.

Cross Reference: Listing 16.2.6.5

Source: ADFT

Program: xxxx.SAS

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Table 14.2.2.4.9

Secondary Analysis: Percentage of Responders who Experience Reduction in mTUG Score from Baseline to Week 76 - Part A + B
Full Analysis Set

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
mTUG Score from Baseline to Week 76			
n	xx	xx	xx
Any positive reduction m (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
1-sided P value		0.xxxx	0.xxxx

Abbreviations: mTUG = Modified Timed Up and Go, CI = Confidence Interval, IMP = Investigational Medicinal Product, CI = Confidence interval.

Note: n is total number of subjects who have an assessment visit at baseline and Week 76.

Note: Count, percentage and 95% CI using the Clopper-Pearson method were computed using observed data. The 1-sided P-value was calculated using the Fisher's exact test where missing mTUG scores were imputed using multiple imputation as described in SAP section 11.1.1. The exact p-values were converted to Z-statistics via an inverse normal cumulative distribution function and Rubin's rules were applied to the resulting Z-statistics across the multiply-imputed datasets to obtain an overall p-value comparing each treatment group to Placebo.

Cross Reference: Listing 16.2.6.5

Source: ADFT, ADMI

Program: xxxx.SAS

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Table 14.2.2.5
Summary of Multiplicity Testing Results - Part A + B
Full Analysis Set

Endpoint	0.5 mg/kg vs Placebo	2.0 mg/kg vs Placebo
Endpoint 1: IBMFRS	x.xxx*	x.xxx
Endpoint 2: MMT 12	x.xxx	x.xxx
Endpoint 3: Grip Strength: Dominant Hand	x.xxx	x.xxx
Endpoint 4: Quadricep Strength: Dominant Leg	x.xxx	x.xxx
Endpoint 5: mTUG.	x.xxx	x.xxx

Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, MMT = Manual Muscle Testing, mTUG = Modified Timed Up and Go.

Note: The p-values are based on the analysis of the primary and secondary efficacy endpoints at Week 76. Null hypotheses are based on the primary and secondary efficacy endpoints with a one-sided significant level of 0.025 level.

Note: The asterisk("*") indicates the test is significant using a one-sided significance level of 0.5% for 0.5mg/kg vs. Placebo and a significance level of 2% for 2.0mg/kg vs. Placebo.

Cross Reference: Table 14.2.1.1.2, Table 14.2.2.1.2, Table 14.2.2.2.2a, Table 14.2.2.3.2a, Table 14.2.2.4.2.

Source: ADMI

Program: xxxx.SAS

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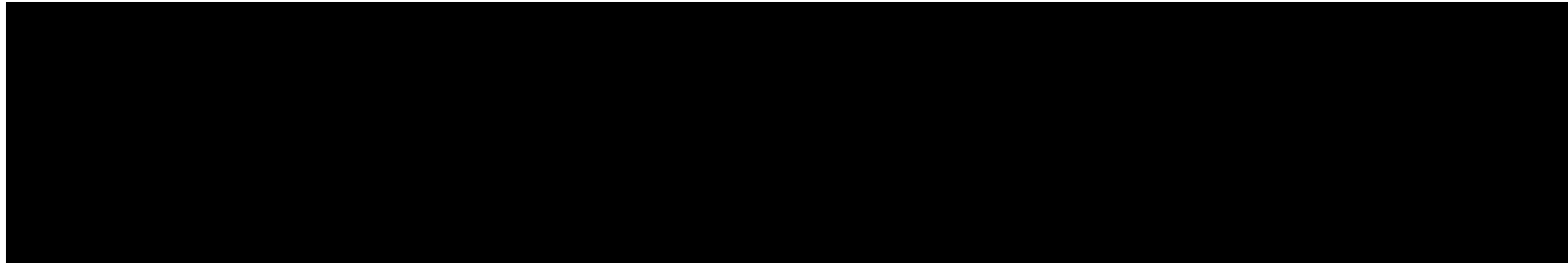
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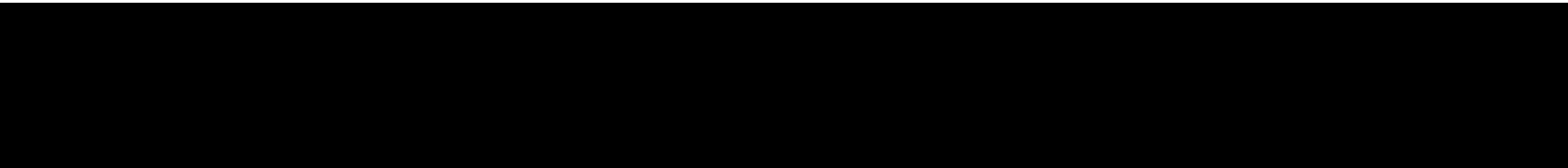
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xx, xx	xx, xx	xx, xx
xx	xx	xx
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xx.x	xx.x	xx.x
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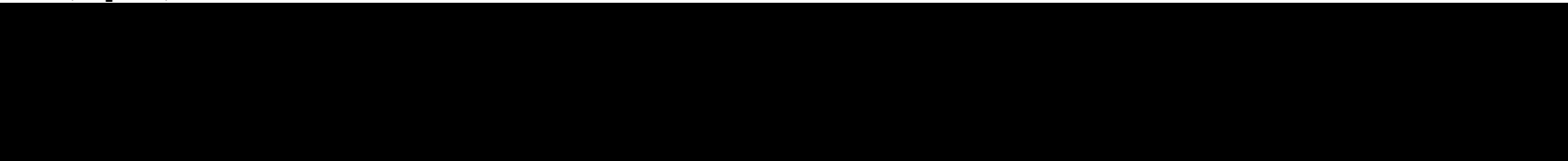
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Table 14.2.4.1.1
Summary of SF-36V2 Scores and Change from Baseline by visit - Part A + B
Full Analysis Set

<PCS/MCS/xx Domain> Score			
Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)			
n	xx	xx	xx
Mean (SD)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)
Median	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Week 8			
n	xx	xx	xx
Mean (SD)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)
Median	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Week 8 Change from Baseline			
n	xx	xx	xx
Mean (SD)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)
Median	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Repeat for Week 16, 32, 64, 76			

Abbreviations: SF-36v2 = Short Form 36-item Health Survey Version 2, PCS = Physical Component Summary, MCS = Mental Component Summary, Min = Minimum, Max = Maximum, SD = Standard Deviation, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Cross Reference: Listing 16.2.6.9

Source: ADQS

Program: xxxx.SAS

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PROGRAMMING NOTE:

The 8 domain scores include physical functioning physical role limitations, bodily pain, general health perceptions, energy/vitality, social functioning, emotional role limitations and mental health score.

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Table 14.2.4.1.2
Mean Change from Baseline in SF-36V2 by Visit - Part A + B
Full Analysis Set

<PCS/MCS/xx Domain> Score

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline by Visit			
n	xx	xx	xx
Mean (SD)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)	xx.xxx (xx.xxxx)
Median	xx.xxx	xx.xxx	xx.xxx
Min, Max	xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
LS Mean of Change	xx.xxx	xx.xxx	xx.xxx
95% CI	xx.xxx, xx.xxx	xx.xxx, xx.xxx	xx.xxx, xx.xxx
LS Mean Difference of Change (vs Placebo)		xx.xxx	xx.xxx
95% CI		xx.xxx, xx.xxx	xx.xxx, xx.xxx
2-sided P value		0.xxxx	0.xxxx
Repeat for Week 16, 32, 64, 76			

Abbreviations: SF-36v2 = Short Form 36-item Health Survey Version 2, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Note: The MMRM model includes fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect, with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure.

Cross Reference: Listing 16.2.6.9

Source: ADQS

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Table 14.2.4.2.1
Summary of EQ-5D-5L Score and Change from Baseline by Visit - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Week 8			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Week 8 Change from Baseline			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Repeat for Week 16, 32, 64, 76 etc			

Abbreviations: EQ-5D-5L = EuroQol 5-dimension 5-level Quality of Life, Quality-of-Life Questionnaire, Min = Minimum, Max = Maximum, SD = Standard Deviation, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Cross Reference: Listing 16.2.6.10

Source: ADQS

Program: xxxx.SAS

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Table 14.2.4.2.2
Mean Change from Baseline in EQ-5D-5L Score by Visit - Part A + B
Full Analysis Set

Visit	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Week 8			
Change from Baseline by Visit			
n	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
LS Mean of Change	xx.x	xx.x	xx.x
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
LS Mean Difference of Change (vs Placebo)		xx.x	xx.x
95% CI		xx.x, xx.x	xx.x, xx.x
2-sided P value		0.xxxx	0.xxxx
Repeat for Week 16, 32, 64, 76 etc			

Abbreviations: EQ-5D-5L = EuroQol 5-dimension 5-level Quality of Life, Min = Minimum, Max = Maximum, SD = Standard Deviation, LS = Least Squares, CI = Confidence Interval, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Note: The Change from Baseline is analyzed using a mixed model repeated measures (MMRM). The model includes fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline [REDACTED] score as a covariate, and subject as the repeated random effect, with <unstructured covariance, Toeplitz, heterogeneous autoregressive with lag (1), autoregressive (1), compound symmetry> covariance structure.

Cross Reference: Listing 16.2.6.10

Source: ADQS

Program: xxxx.SAS

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	xx	xx	xx
	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)
	xx (xx.x)	xx (xx.x)	xx (xx.x)

Program: xxxx.SAS

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Table 14.2.5
Exit Survey (Clinical Trial Experience) - Part A + B
Full Analysis Set

Visit	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)
Did the Subject complete the Survey			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Question 1: Treatment Expectations			
How well did the actual results of the treatment align with your expectations?			
Far below my expectations	xx (xx.x)	xx (xx.x)	xx (xx.x)
Below my expectations	xx (xx.x)	xx (xx.x)	xx (xx.x)
Met my expectations	xx (xx.x)	xx (xx.x)	xx (xx.x)
Exceeded my expectations	xx (xx.x)	xx (xx.x)	xx (xx.x)
Far exceeded my expectations	xx (xx.x)	xx (xx.x)	xx (xx.x)
Question 2: Dosing Regimen & Visit Schedule			
How would you rate your ability to follow the treatment (8 weeks) and visit schedule?			
Very easy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Easy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neutral	xx (xx.x)	xx (xx.x)	xx (xx.x)
Difficult	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very difficult	xx (xx.x)	xx (xx.x)	xx (xx.x)
Question 3: Changes in Symptoms and Functioning			
From the start of the study, what is your assessment of the change in your functional abilities during the following activities.			
a. When eating your meals, please assess your efforts when swallowing food.			
Much improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
No change	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat worse	xx (xx.x)	xx (xx.x)	xx (xx.x)
Much worse	xx (xx.x)	xx (xx.x)	xx (xx.x)
Could not perform	xx (xx.x)	xx (xx.x)	xx (xx.x)
b. Please assess your efforts with hand and finger movements during your daily routine.			
Much improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
No change	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat worse	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Much worse	xx (xx.x)	xx (xx.x)	xx (xx.x)
Could not perform			
c. Please assess your efforts when moving from a seated to a standing position?			
Much improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
No change	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat worse	xx (xx.x)	xx (xx.x)	xx (xx.x)
Much worse			
Could not perform	xx (xx.x)	xx (xx.x)	xx (xx.x)
d. Please assess your efforts when walking during your daily activities.			
Much improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat improved	xx (xx.x)	xx (xx.x)	xx (xx.x)
No change	xx (xx.x)	xx (xx.x)	xx (xx.x)
Somewhat worse	xx (xx.x)	xx (xx.x)	xx (xx.x)
Much worse			
Could not perform	xx (xx.x)	xx (xx.x)	xx (xx.x)
Question 4: Thoughts on Study Procedures and Participation			
How clearly were the study activities explained to you?			
Very unclear	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unclear	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neutral	xx (xx.x)	xx (xx.x)	xx (xx.x)
Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very clear	xx (xx.x)	xx (xx.x)	xx (xx.x)
Question 5: Experience with Clinical Trial Participation			
Overall, how would you rate your experience participating in this clinical trial?			
Very poor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Poor	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fair	xx (xx.x)	xx (xx.x)	xx (xx.x)
Good	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very good	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note: Percentages are based on total number of subjects in full analysis set in each treatment group. Due the timing of the protocol change and a significant number of participants already exited the study, the survey on the Clinical Trial Experience was administered to a subset of USA participants.

Cross Reference: Listing 16.2.6.12

Source: ADQS

Program: xxxx.SAS

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Table 14.2.7.1
Lymphocyte Subset: Summary by Visit and Change from Baseline - Part A + B
Pharmacodynamic Analysis Set

CD8+ [CD3+CD8+] (ABS / μ l of blood)

Visit	Values	Statistics	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)	Actual	n	xx	xx	xx
		Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
		Median	xx.xx	xx.xx	xx.xx
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 32	Actual	n	xx	xx	xx
		Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
		Median	xx.xx	xx.xx	xx.xx
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	CFB	n	xx	xx	xx
		Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
		Median	xx.xx	xx.xx	xx.xx
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	PCFB	n	xx	xx	xx
		Mean (SD)	xx.xx (xx.xxx)	xx.xx (xx.xxx)	xx.xx (xx.xxx)
		Median	xx.xx	xx.xx	xx.xx
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for Week 76 etc					

Abbreviations: Abs/ μ l = Absolute Value per Microliter, SD = Standard Deviation, Min = Minimum, Max = Maximum, CFB = Change from Baseline, PCFB = Percentage Change from Baseline, ET = Early Termination Visit, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Cross Reference: Listing 16.2.8.1.7.1a , 16.2.8.1.7.1b, 16.2.8.1.7.1c, 16.2.8.1.7.1d

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

1. This table for all subjects
2. Parameters include the following lbtest. Display label as follows:
 - a. Tregs [3+4+CD127-1oCD25+] (ABS / μ l of blood)
 - b. Tregs KLRG1+ [3+4+CD127-1oCD25+KLRG1+] (ABS / μ l of blood)
 - c. CD4+ [CD3+CD4+] (ABS / μ l of blood)

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- d. CD4+KLRG1+ [3+CD4+KLRG1+] (ABS / μ l of blood)
- e. CD8+ [CD3+CD8+] (ABS / μ l of blood)
- f. CD8+KLRG1+ [3+CD8+KLRG1+] (ABS / μ l of blood)
- g. CD8+KLRG1+CD57+ [3+CD8+KLRG1+CD57+] (ABS / μ l of blood)
- h. CD8+CD57+ [3+CD8+CD57+] (ABS / μ l of blood)
- i. NK [CD3-CD56+/CD16+] (ABS / μ l of blood)
- j. NK KLRG1+ [3-56+/16+KLRG1+] (ABS / μ l of blood)
- k. NKT [CD3+CD56+] (ABS / μ l of blood)
- l. NKT KLRG1+ [3+56+KLRG1+] (ABS / μ l of blood)
- m. CD19+ [CD3-CD19+] (ABS / μ l of blood)
- n. CD20+ [CD3-CD20+] (ABS / μ l of blood)
- o. CD20+ KLRG1+ [3-CD20+KLRG1+] (ABS / μ l of blood)

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Table 14.2.7.2
Lymphocyte Subset: Summary by Visit and Change from Baseline - Part B Intensive
Pharmacodynamic Analysis Set

CD8+ [CD8+KLRG1+] (ABS / μ l of blood)

Visit	Values	Statistics	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Week 2	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	CFB	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	PCFB	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx

Repeat for Week 1
2, 4, 8, 16, 32,
64, and 76 etc

Abbreviations: Abs/ μ l = Absolute Value per microliter, SD = Standard deviation, Min = Minimum, Max = Maximum, CFB = Change from Baseline, PCFB = Percentage change from Baseline, ET = Early Termination Visit, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Cross Reference: Listing 16.2.8.1.7.1a , 16.2.8.1.7.1b, 16.2.8.1.7.1c, 16.2.8.1.7.1d

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

1. This table is for 19 patients with more timepoints, it will include also weeks 2, 4, 8, 16, and 64.
2. Parameters include the following lbtest. Display label as follows:
 - a. Tregs [3+4+CD127-loCD25+] (ABS / μ l of blood)
 - b. Tregs KLRG1+ [3+4+CD127-loCD25+KLRG1+] (ABS / μ l of blood)
 - c. CD4+ [CD3+CD4+] (ABS / μ l of blood)

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- d. CD4+KLRG1+ [3+CD4+KLRG1+] (ABS / μ l of blood)
- e. CD8+ [CD3+CD8+] (ABS / μ l of blood)
- f. CD8+KLRG1+ [3+CD8+KLRG1+] (ABS / μ l of blood)
- g. CD8+KLRG1+CD57+ [3+CD8+KLRG1+CD57+] (ABS / μ l of blood)
- h. CD8+CD57+ [3+CD8+CD57+] (ABS / μ l of blood)
- i. NK [CD3-CD56+/CD16+] (ABS / μ l of blood)
- j. NK KLRG1+ [3-56+/16+KLRG1+] (ABS / μ l of blood)
- k. NKT [CD3+CD56+] (ABS / μ l of blood)
- l. NKT KLRG1+ [3+56+KLRG1+] (ABS / μ l of blood)
- m. CD19+ [CD3-CD19+] (ABS / μ l of blood)
- n. CD20+ [CD3-CD20+] (ABS / μ l of blood)
- o. CD20+ KLRG1+ [3-CD20+KLRG1+] (ABS / μ l of blood)

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Table 14.2.7.3
Lymphocyte Subset : Summary by Visit and Change from Baseline - Part C
Part C Pharmacodynamic Analysis Set

CD8+ [CD8+KLRG1+] (ABS / µl of blood)

Visit	Values	Statistics	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)
Day 1 (Baseline)	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Part C Visit 1	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	CFB	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	PCFB	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Part C Month 3	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	CFB	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	PCFB	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx

Repeat for Part C Month
6, 9 etc

Abbreviations: Abs/µl = Absolute Value per microliter, SD = Standard Deviation, Min = Minimum, Max = Maximum, CFB = Change from Baseline, PCFB = Percentage Change from Baseline, ET = Early Termination Visit, IMP = Investigational Medicinal Product.

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Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Part C Baseline (part C visit 1) is defined as the value collected at Part A or B W80 visit.

Note: Change from Baseline and percent change from baseline is only calculated for subjects with data at the given visit and the baseline value (on Day 1) prior to first administration.

Cross Reference: Listing 16.2.8.1.7.2

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

1. Parameters include the following lbtest. Display label as follows:

- a. Tregs [3+4+CD127-loCD25+] (ABS / μ l of blood)
- b. Tregs KLRG1+ [3+4+CD127-loCD25+KLRG1+] (ABS / μ l of blood)
- c. CD4+ [CD3+CD4+] (ABS / μ l of blood)
- d. CD4+KLRG1+ [3+CD4+KLRG1+] (ABS / μ l of blood)
- e. CD8+ [CD3+CD8+] (ABS / μ l of blood)
- f. CD8+KLRG1+ [3+CD8+KLRG1+] (ABS / μ l of blood)
- g. CD8+KLRG1+CD57+ [3+CD8+KLRG1+CD57+] (ABS / μ l of blood)
- h. CD8+CD57+ [3+CD8+CD57+] (ABS / μ l of blood)
- i. NK [CD3-CD56+/CD16+] (ABS / μ l of blood)
- j. NK KLRG1+ [3-56+/16+KLRG1+] (ABS / μ l of blood)
- k. NKT [CD3+CD56+] (ABS / μ l of blood)
- l. NKT KLRG1+ [3+56+KLRG1+] (ABS / μ l of blood)
- m. CD19+ [CD3-CD19+] (ABS / μ l of blood)
- n. CD20+ [CD3-CD20+] (ABS / μ l of blood)
- o. CD20+ KLRG1+ [3-CD20+KLRG1+] (ABS / μ l of blood)

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Table 14.2.7.4

Lymphocyte Subset : Shift of Reference Range Indicators by Visit from Baseline - Part A + B
Pharmacodynamic Analysis Set

CD4+ [CD3+CD4+] (ABS / µl of blood)

Visit	Shift	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
CD4+ (Absolute Value)					
Week 32	n	xx	xx	xx	xx
	Normal -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat for Week 76

Repeat for CD8+, CD19+

Abbreviations: Abs/µl = Absolute Value per microliter, IMP = Investigational Medicinal Product

Note: n = number of subjects with both baseline value and post-baseline value at each visit, N = number of participants at each treatment group and Total.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on number of subjects in Pharmacodynamic analysis set in each treatment group at each visit.

Cross Reference: Listing 16.2.8.1.7.1a , 16.2.8.1.7.1b, 16.2.8.1.7.1d

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Notes:

1. Apply to total parent populations only, not KLRG1 populations
2. Parameters include the following lbtest. Display label as follows:
 - a. CD4+ [CD3+CD4+] (ABS / µl of blood)
 - b. CD8+ [CD3+CD8+] (ABS / µl of blood)
 - c. CD19+ [CD3-CD19+] (ABS / µl of blood)
3. Only results from nominal visits will be summarized (i.e., results from unscheduled visits will not be presented).

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Table 14.2.7.5

Lymphocyte Subset : Shift of Reference Range Indicators by Visit from Baseline - Part B Intensive
Pharmacodynamic Analysis Set

CD4+ [CD3+CD4+] (ABS / μ l of blood)

Visit	Shift	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)
CD4+ (Absolute Value)				
Week 1	n	xx	xx	xx
	Normal -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat for Week 2, 4, 8,
16, 32, 64, and 76 etc

Repeat for CD8+ ABS, CD19+
ABS

Abbreviations: Abs/ μ l = Absolute Value per microliter, IMP = Investigational Medicinal Product

Note: n = number of subjects with both baseline value and post-baseline value at each visit, N = number of participants at each treatment group and Total.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on number of subjects in Safety analysis set in each treatment group at each visit.

Cross Reference: Listing 16.2.8.1.7.1a , 16.2.8.1.7.1b, 16.2.8.1.7.1d

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Notes:

1. Apply to total total lymphocytes only, not KLRG1 populations-this is only for CD4 T cells, CD8 T cells and B cells only these three analytes
2. This table is for a subset of patients with more timepoints, it will include also weeks 2, 4, 8, 16, 32, and 64 and 76 .
3. Parameters include the following lbttest. Display label as follows:
 - a. CD4+ [CD3+CD4+] (ABS / μ l of blood)

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b. CD8+ [CD3+CD8+] (ABS / μ l of blood)

c. CD19+ [CD3-CD19+] (ABS / μ l of blood)

4. Only results from nominal visits will be summarized (i.e., results from unscheduled visits will not be presented).

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Table 14.2.7.6

Lymphocyte Subset : Shift of Reference Range Indicators by Visit from Baseline - Part C

Part C Pharmacodynamic Analysis Set

CD4+ [CD3+CD4+] (ABS / μ l of blood)

Visit	Shift	Placebo	ABC008 0.5mg/kg	ABC008 2.0mg/kg
		(N=XX) n (%)	(N=XX) n (%)	(N=XX) n (%)
CD4+ (Absolute Value)				
Part C month 3	n	xx	xx	xx
	Normal -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Normal -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Low -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)
	High -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat for Part C month 3
6, 9, etc

Repeat for CD8+ , CD19+

Note: n = number of subjects with both baseline value and post-baseline value at each visit, N = number of participants at each treatment group and Total.

Note: Part C Baseline is defined as the value collected at Part A or B W80 visit.

Note: Percentages are based on number of subjects in Safety analysis set in each treatment group at each visit.

Cross Reference: Listing 16.2.8.1.7.2

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Notes:

1. Apply to total total lymphocytes only, not KLRG1 populations
2. Parameters include the following lbtest. Display label as follows:
 - a. CD4+ [CD3+CD4+] (ABS / μ l of blood)
 - b. CD8+ [CD3+CD8+] (ABS / μ l of blood)
 - c. CD19+ [CD3-CD19+] (ABS / μ l of blood)
3. Only results from nominal visits will be summarized (i.e., results from unscheduled visits will not be presented).

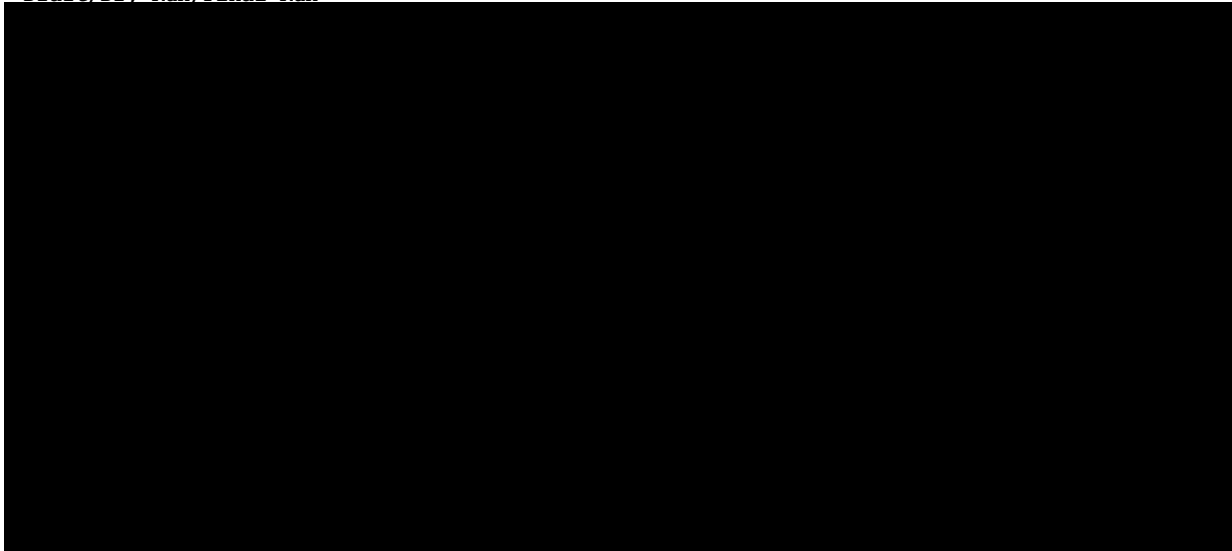
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Table 14.2.10

Summary of Thyroid Hormones by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.2.7.1 for Thyroid Hormones (T4, TSH)

Cross Reference: Listing 16.2.8.1.6

Source: ADLB

Table 14.2.10C

Summary of Thyroid Hormones by Visit and Change from Baseline in Conventional Units - Part A + B
Safety Analysis Set

Repeat Table 14.2.7.1 for Thyroid Hormones (T4, TSH) in conventional units

Cross Reference: Listing 16.2.8.1.6C

Source: ADLC

Table 14.2.11

Summary of Immunoglobulins by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.2.7.1 for Immunoglobulins (M protein, and light chain ratio assessment)

Cross Reference: Listing 16.2.8.2.5

Source: ADMB

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Table 14.3.1.1.1
Treatment-Emergent Adverse Events - Overall Summary - Part A + B
Safety Analysis Set

	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subjects with at least one				
AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE related to study drug as assessed by the investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE leading to study drug discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE leading to study discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs leading to death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs of Special Interest	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs of Special Interest related to study drug	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs of Special Interest leading to study drug discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAEs of Special Interest leading to study discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: AE = Adverse event; TEAE = Treatment-emergent adverse event.

Note: Adverse events are coded using MedDRA version 25.1.

Note: A TEAE is defined as an AE that first appears or worsens after initiation of study drug.

Note: Percentages are based on total number of subjects in Safety analysis set in each treatment group or Total.

Note: An AE with missing relationship to study drug will be considered as related to study drug.

Cross Reference: Listing 16.2.7.1.1

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

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Table 14.3.1.1.2
Treatment-Emergent Adverse Events - Overall Summary - Part C
Safety Analysis Set

Repeat Table 14.3.1.1.1 for AE in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Cross Reference: Listing 16.2.7.1.2

Source: ADAE

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Table 14.3.1.2.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

System Organ Class Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subjects with any TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				

Abbreviations: TEAE = Treatment-emergent adverse event, MedDRA = Medical dictionary for regulatory activities.

Note: Adverse events are coded using MedDRA version 25.1.

Note: A TEAE is defined as an AE that first appears or worsens after initiation of study drug.

Note: Percentages are based on total number of subjects in Safety analysis set in each treatment group or Total. At each level of summarization, subjects who experienced more than one event are counted only once within each SOC and PT.

Cross Reference: Listing 16.2.7.1.1

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note: [a] Sort by decreasing frequency in Total group by SOC, then PT and then alphabetically

[b] Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT

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Table 14.3.1.2.2
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.2.1 for TEAE in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Cross Reference: Listing 16.2.7.1.2

Source: ADAE

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Table 14.3.1.3.1
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Intensity - Part A + B
Safety Analysis Set

System Organ Class Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subjects with any TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade = 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for Preferred Term 2, 3, ..	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
Repeat System Organ Class 2, 3, ..	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				

Abbreviations: TEAE = Treatment-emergent adverse event, MedDRA = Medical dictionary for regulatory activities, NCI-CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events.

Note: Adverse events are coded using MedDRA version 25.1.

Note: A TEAE is defined as an AE that first appears or worsens after initiation of study drug.

Note: Percentages are based on total number of subjects in Safety analysis set in each treatment group or Total. At each level of summarization, subjects who experienced more than one event are counted only once with the maximum severity within each SOC and PT.

Note: An adverse event with missing intensity will be considered as Grade = 5.

Cross Reference: Listing 16.2.7.1.1

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

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Programming Note: [a] Sort by decreasing frequency in Total group by SOC, then PT and then alphabetically
[b] Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT.

Table 14.3.1.3.2

Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Intensity - Part C
Safety Analysis Set

Repeat Table 14.3.1.3.1 for TEAE in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Cross Reference: Listing 16.2.7.1.2

Source: ADAE

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Table 14.3.1.4.1
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Relationship - Part A + B
Safety Analysis Set

System Organ Class Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subjects with any TEAEs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for Preferred Term 2, 3, ..	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
Repeat System Organ Class 2, 3, ..	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: TEAE = Treatment-emergent adverse event, MedDRA = Medical dictionary for regulatory activities.

Note: Adverse events are coded using MedDRA version 25.1.

Note: A TEAE is defined as an AE that first appears or worsens after initiation of study drug.

Note: Percentages are based on total number of subjects in Safety analysis set in each treatment group or Total. At each level of summarization, subjects who experienced more than one event are counted only once with the maximum severity within each SOC and PT.

Note: An AE with missing relationship to study drug will be considered as related to study drug.

Cross Reference: Listing 16.2.7.1.1

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note:**[a] Sort by decreasing frequency in Total group by SOC, then PT and then alphabetically****[b] Any uncoded terms to be displayed under a SOC 'Uncoded'**

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Table 14.3.1.4.2

Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Relationship Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.4.1 for TEAE in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Cross Reference: Listing 16.2.7.1.2

Source: ADAE

Table 14.3.1.5.1

Treatment-related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for TEAE Leading to Death

Table 14.3.1.5.2

Treatment-related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.5.1 for TEAE Leading to Death in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Cross Reference: Listing 16.2.7.1.2

Source: ADAE

Table 14.3.1.6.1

Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 with Treatment-Emergent Serious Adverse Events

Cross Reference: Listing 16.2.7.2.1

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Table 14.3.1.6.2

Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.6.1 for Serious Treatment-Emergent Adverse Events in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Cross Reference: Listing 16.2.7.2.2

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Table 14.3.1.7.1

Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for TEAE Leading to Study Medication Discontinuation

Table 14.3.1.8.1

Treatment-Emergent Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for TEAE Leading to Study Discontinuation

Table 14.3.1.8.2

Treatment-Emergent Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.8.1 for TEAE Leading to Study Discontinuation in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Table 14.3.1.9.1

Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for TEAE Leading to Death

Table 14.3.1.9.2

Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.9.1 for TEAE Leading to Death in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Table 14.3.1.10.1

Treatment-related Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 with Treatment-Emergent Serious Adverse Events

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Table 14.3.1.10.2

Treatment-related Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.10.1 with Treatment-Emergent Serious Adverse Events in Part C

Add an additional footnote "Note: Only include subjects that enrolled in Part C and adverse event that appears or worsens after end of treatment".

Table 14.3.1.11

Treatment-Emergent Adverse Events with Onset Within 24 hours From the Start of Any Study Medication Administration by System Organ
Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for TEAE onset within 24 hours from the start of any study medication administration

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Table 14.3.1.12.1
Treatment-Emergent Adverse Events of Special Interest - Part A + B
Safety Analysis Set

System Organ Class Preferred Term	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Subjects with any AESI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				
System Organ Class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
...				

Abbreviations: AESI = Adverse events of special interest, MedDRA = Medical dictionary for regulatory activities.

Note: Adverse events are coded using MedDRA version 25.1.

Note: A TEAE is defined as an AE that first appears or worsens after initiation of study drug.

Note: Percentages are based on total number of subjects in Safety analysis set in each treatment group or Total. At each level of summarization, subjects who experienced more than one event are counted only once within each SOC and PT.

Cross Reference: Listing 16.2.7.3.1

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note: [a] Sort by decreasing frequency in Total group by SOC, then PT and then alphabetically**[b] Any uncoded terms to be displayed under a SOC 'Uncoded' and then the verbatim term for the PT.**

Table 14.3.1.12.2
Treatment-Emergent Adverse Events of Special Interest - Part C
Safety Analysis Set

Repeat Table 14.3.1.12.1 for AESI in Part C

Cross Reference: Listing 16.2.7.3.2

Source: ADAE

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Table 14.3.1.13.1

Treatment-Emergent Adverse Events of Special Interest Related to Study Drug by System Organ Class and Preferred Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for AESI related to study drug

Table 14.3.1.13.2

Treatment-Emergent Adverse Events of Special Interest Related to Study Drug by System Organ Class and Preferred Term - Part C
Safety Analysis Set

Repeat Table 14.3.1.13.1 for AESI related to study drug in Part C

Table 14.3.1.14

Treatment-Emergent Adverse Events of Special Interest Leading to Study Drug Discontinuation by System Organ Class and Preferred
Term - Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for AESI leading to study drug discontinuation

Table 14.3.1.15.1

Treatment-Emergent Adverse Events of Special Interest Leading to Study Discontinuation by System Organ Class and Preferred Term -
Part A + B
Safety Analysis Set

Repeat Table 14.3.1.2.1 for AESI leading to study discontinuation

Table 14.3.1.15.2

Treatment-Emergent Adverse Events of Special Interest Leading to Study Discontinuation by System Organ Class and Preferred Term -
Part C
Safety Analysis Set

Repeat Table 14.3.1.15.1 for AESI leading to study discontinuation in Part C

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Table 14.3.4.1.1.1
Hematology: Summary by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Laboratory parameter (unit)

Visit	Values	Statistics	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Day 1 (Baseline)	Actual	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Day X	Actual	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	CFB	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Repeat for Week 2,
4, 8, 16, 24, 28, 32
40, 48, 56, 64, 72
and 76 etc

Abbreviations: SD = Standard deviation, Min = Minimum, Max = Maximum, CFB = Change from Baseline, ETV = Early Termination Visit, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Note: Only Part A patients had a Week 20 visit per protocol.

Cross Reference: Listing 16.2.8.1.2

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note:

Hematology include: Hematology: hemoglobin, hematocrit, red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin, concentration, white blood cell count with differential (e.g., basophils, eosinophils, lymphocytes, monocytes, neutrophils), platelet count, CD4, CD8, CD19, and CD4:CD8.

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Hematology: Summary by Visit and Change from Baseline in Conventional Units- Part A + B
Table 14.3.4.1.1.1C
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 in conventional units

Cross Reference: Listing 16.2.8.1.2C

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note:

Hematology include: Hematology: hemoglobin, hematocrit, red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin, concentration, white blood cell count with differential (e.g., basophils, eosinophils, lymphocytes, monocytes, neutrophils), platelet count, CD4, CD8,CD19, and CD4:CD8.

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Table 14.3.4.1.1.2
Hematology: Shift of Reference Range Indicators by Visit from Baseline - Part A + B
Safety Analysis Set

Parameter (Unit)	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Visit	n (%)	n (%)	n (%)	n (%)
Shift				
Week 1				
n	xx	xx	xx	xx
Normal -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High -> Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High -> Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High -> High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat for Week 4, 8, 16, 24,
28, 32, 40, 48, 56, 64, 72,
and 76 etc

Abbreviations: IMP = Investigational Medicinal Product

Note: n=number of subjects with both baseline value and post-baseline value at each visit, N=number of participants at each treatment group and Total.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on number of subjects in Safety Analysis Set in each treatment group or Total at each visit.

Cross Reference: Listing 16.2.8.1.2

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note:

Hematology include: Hematology: hemoglobin, hematocrit, red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin, concentration, white blood cell count with differential (e.g., basophils, eosinophils, lymphocytes, monocytes, neutrophils), platelet count, CD4, CD8,CD19, and CD4:CD8.

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Table 14.3.4.1.1.2C

Hematology: Shift of Reference Range Indicators by Visit from Baseline in Conventional Units- Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Hematology in Conventional Units

Cross Reference: Listing 16.2.8.1.2C

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note:

Hematology include: Hematology: hemoglobin, hematocrit, red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin, concentration, white blood cell count with differential (e.g., basophils, eosinophils, lymphocytes, monocytes, neutrophils), platelet count, CD4, CD8,CD19, and CD4:CD8.

Table 14.3.4.1.2.1

Blood Chemistry: Summary by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 for Blood Chemistry

Chemistry include: Clinical chemistry: albumin, alanine aminotransferase, aldolase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, C-reactive protein, calcium, [REDACTED] creatinine, gamma-glutamyl transpeptidase, glucose, lactate dehydrogenase, potassium, sodium chloride, total bilirubin, total protein, uric acid. eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation.

Cross Reference: Listing 16.2.8.1.3

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Table 14.3.4.1.2.1C

Blood Chemistry: Summary by Visit and Change from Baseline in Conventional Units - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 for Blood Chemistry in conventional units

Chemistry include: Clinical chemistry: albumin, alanine aminotransferase, aldolase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, C-reactive protein, calcium, [REDACTED] creatinine, gamma-glutamyl transpeptidase, glucose, lactate dehydrogenase, potassium, sodium chloride, total bilirubin, total protein, uric acid. eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation.

Cross Reference: Listing 16.2.8.1.3C

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

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Table 14.3.4.1.2.2

Blood Chemistry: Shift of Reference Range Indicators by Visit from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Blood Chemistry

Chemistry include: Clinical chemistry: albumin, alanine aminotransferase, aldolase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, C-reactive protein, calcium, [REDACTED] creatinine, gamma-glutamyl transpeptidase, glucose, lactate dehydrogenase, potassium, sodium chloride, total bilirubin, total protein, uric acid. eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation.

Cross Reference: Listing 16.2.8.1.3

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Table 14.3.4.1.2.2C

Blood Chemistry: Shift of Reference Range Indicators by Visit from Baseline in Conventional Units- Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Blood Chemistry in conventional units

Chemistry include: Clinical chemistry: albumin, alanine aminotransferase, aldolase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, C-reactive protein, calcium, [REDACTED] creatinine, gamma-glutamyl transpeptidase, glucose, lactate dehydrogenase, potassium, sodium chloride, total bilirubin, total protein, uric acid. eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation.

Cross Reference: Listing 16.2.8.1.3C

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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Table 14.3.4.1.3.1

Urinalysis: Summary of Continuous Parameters by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 for Urinalysis

Cross Reference: Listing 16.2.8.1.4

Do not include the following footnote: Note: Only Part A patients had a Week 20 visit per protocol.

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Urinalysis: color, appearance, specific gravity, pH, protein, glucose, ketones, bilirubin, blood, urobilinogen, nitrite, leukocyte esterase with reflex microscopic analysis

Table 14.3.4.1.3.1C

Urinalysis: Summary of Continuous Parameters by Visit and Change from Baseline in Conventional Units - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 for Urinalysis in conventional units

Do not include the following footnote: Note: Only Part A patients had a Week 20 visit per protocol.

Cross Reference: Listing 16.2.8.1.4C

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

PROGRAMMING NOTE:

Urinalysis: color, appearance, specific gravity, pH, protein, glucose, ketones, bilirubin, blood, urobilinogen, nitrite, leukocyte esterase with reflex microscopic analysis

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Table 14.3.4.1.3.2
Urinalysis: Summary of Categorical Parameters by Visit - Part A + B
Safety Analysis Set

Laboratory Parameter (Unit)

Visit category	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Day 1 (Baseline))				
n	xx	xx	xx	xx
Result Category 1, n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Result Category 2, n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Repeat for Week 2, 4, 8, 16, 24, 28, 32, 40, 48, 56, 64, 72 and 76 etc				

n = Number of participants.

Percentages are based on total number of participants in each treatment group.

Baseline is defined as the last non-missing measurement prior to the date of study treatment administration.

Cross Reference: Listing 16.2.8.1.4

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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PROGRAMMING NOTE:

Urinalysis: color, appearance, protein, glucose, blood, urobilinogen, nitrite, leukocyte esterase with reflex microscopic analysis

Laboratory Parameters will be listed in alphabetical order.

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Table 14.3.4.1.3.3
Urinalysis: Normality Shift by Visit from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Urinalysis

Table 14.3.4.1.3.3C
Urinalysis: Normality Shift by Visit from Baseline in Conventional Units- Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Urinalysis in conventional units

Cross Reference: Listing 16.2.8.1.4C

Source: ADLC

Program: xxxx.SAS

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Table 14.3.4.1.4.1
Complement: Summary by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 for Complement levels

Cross Reference: Listing 16.2.8.1.5

Source: ADLB

Program: xxxx.SAS

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Complement: C3, C4, and CH50.

Table 14.3.4.1.4.1C
Complement: Summary by Visit and Change from Baseline in Conventional Units - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.1 for Complement levels in conventional units

Cross Reference: Listing 16.2.8.1.5C

Source: ADLC

Program: xxxx.SAS

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Complement: C3, C4, and CH50.

Table 14.3.4.1.4.2
Complement: Shift of Reference Range Indicators by Visit from Baseline - Part A + B
Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Complement levels

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Table 14.3.4.1.4.2C

Complement: Shift of Reference Range Indicators by Visit from Baseline in Conventional Units - Part A + B

Safety Analysis Set

Repeat Table 14.3.4.1.1.2 for Complement levels in Conventional Units

Cross Reference: Listing 16.2.8.1.5C

Source: ADLC

Program: xxxx.SAS

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Table 14.3.4.2.1
Vital Signs: Summary by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Test (SI unit) Visit	Values	Statistics	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Systolic blood pressure (mmHg)						
Day 1 (Baseline)	Actual	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Week 1	Actual	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	CFB	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Repeat for Week 8, 16, 20, 32 64, 72
and 76 etc

Repeat for other tests

Abbreviations: SD = Standard deviation; Min = Minimum; Max = Maximum; CFB = Change from Baseline, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Note: Only Part A patients had a Week 20 Visit per protocol

Cross Reference: Listing 16.2.8.2.1

Source: ADVS

Program: xxxx.SAS

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Programming Note:

vital signs include systolic blood pressure (mmHg) , diastolic blood pressure (mmHg) , pulse rate (bpm) , respiratory rate (breaths/minute), and temperature (°C).

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Table 14.3.4.2.2
Vital Signs: Summary of Overall Assessment Results by Visit - Part A + B
Safety Analysis Set

Visit	Overall Assessment	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Day 1 (Baseline)	n	xx	xx	xx	xx
	Normal	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)
	Abnormal - CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 1	n	xx	xx	xx	xx
	Normal	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)
	Abnormal - CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for Week 2, 4, 8, 16, 20, 24, 28, 32 40,48, 56, 64, 72 and 76 etc					

Abbreviations: CS = Clinical significant, NCS = Non-clinical significant

Note: Percentages are based on total number of subjects in safety analysis set in each treatment group or Total.

Cross Reference: Listing 16.2.8.2.1

Source: ADVS

Program: xxxx.SAS

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Table 14.3.4.2.3
Vital Signs: Normality Shift from Baseline to Last Observation - Part A + B
Safety Analysis Set

Shift	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Normal -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> Abnormal - NCS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> Abnormal - CS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> Missing, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal- NCS -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal- NCS -> Abnormal- NCS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal- NCS -> Abnormal - CS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal- NCS -> Missing, n (%)				
Abnormal - CS -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal - CS -> Abnormal- NCS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal - CS -> Abnormal - CS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal - CS -> Missing, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Abnormal- NCS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Abnormal - CS, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Missing, n (%)				

Abbreviations: NCS = Not Clinically Significant, CS = Clinically Significant, IMP = Investigational Medicinal Product.

Note: For Part A and B, the baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on total number of subjects in safety analysis set in each treatment group or Total.

Cross Reference: Listing 16.2.8.2.1

Source: ADVS

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Table 14.3.4.2.4
Vital Signs: Summary of Abnormal Measurements - Part A + B
Safety Analysis Set

	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Subject with at least one post-treatment measurement				
Systolic Blood Pressure, n (%)				
<90 mmHg	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>140 mmHg	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>160 mmHg	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diastolic Blood Pressure, n (%)				
<50 mmHg	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>90 mmHg	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>100 mmHg	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pulse Rate, n (%)				
<60 bpm	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>100 bpm	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Body Weight, n (%)				
Decrease of >=7% from baseline	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Increase of >=7% from baseline	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Temperature, n (%)				
<36.0 °C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>38.0 °C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Respiratory Rate, n (%)				
< 12 BPM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
> 20 BPM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: IMP = Investigational Medicinal Product, bpm = beats per minute, BPM = breaths per minute

Note: For Part A and B, the baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on total number of subjects in safety analysis set in each treatment group or Total.

Cross Reference: Listing 16.2.8.2.1

Source: ADVS

Program: xxxx.SAS

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Table 14.3.4.3.1
ECG: Summary by Visit and Change from Baseline - Part A + B
Safety Analysis Set

Test (unit) Visit	Values	Statistics	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Test (unit)						xx
Day 1 (Baseline)	Actual	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
Week 16	Actual	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx
	CFB	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx	xx, xx

Repeat for Week 20, 32
and 76 etc

Abbreviations: ECG = Electrocardiogram, QTcF = QT Interval Corrected Using Fridericia's Formula, SD = Standard deviation; Min = Minimum; Max = Maximum; CFB = Change from Baseline, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Change from Baseline is only calculated for subjects with data at the given visit and Baseline.

Note: Only Part A patients had a Week 20 visit per protocol.

Cross Reference: Listing 16.2.8.2.2

Source: ADEG

Program: xxxx.SAS

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Programming Note:

ECG include Heart rate, PR interval, QRS interval, QT interval and QTc interval corrected using Fridericia's criteria

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Table 14.3.4.3.2
ECG: Summary of Overall Interpretation by Visit - Part A + B
Safety Analysis Set

Visit	Overall Interpretation	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Day 1 (Baseline)	n	xx	xx	xx	xx
	Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 16	n	xx	xx	xx	xx
	Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for Week 32, and 76					

Abbreviations: ECG = Electrocardiogram, IMP = Investigational Medicinal Product.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on number of subjects in safety analysis set at each visit in each treatment group or Total.

Cross Reference: Listing 16.2.8.2.2

Source: ADEG

Program: xxxx.SAS

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Programming Note:

Summary at Week 20 is only applicable for Part A subjects.

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Table 14.3.4.3.3
ECG: Summary of QTcF Interval Category - Part A + B
Safety Analysis Set

QTc category	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Baseline QTcF interval (msec), n (%)				
n	xx	xx	xx	xx
<=450 (M), <=470 (F)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>450 to <=500 (M), >470 to <=500 (F)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Maximum Post-baseline QTc intervals (msec), n (%)				
n	xx	xx	xx	xx
<=450 (M), <=470 (F)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>450 to <=500 (M), >470 to <=500 (F)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Maximum change from baseline (QTcF interval(msec)), n (%)				
n	xx	xx	xx	xx
<=30	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>30 to <=60	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>60	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Post-baseline Value QTcF interval (msec), n (%) [a]				
n	xx	xx	xx	xx
>450	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>480	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>500	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Abbreviations: ECG = Electrocardiogram, QTcF = QT Interval Corrected Using Fridericia's Formula, M = Males, F = Females, IMP = Investigational Medicinal Product.

Note: Baseline is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on total number of subjects in safety analysis set in each treatment group or Total.

[a] Subjects can [REDACTED] into multiple categories.

Cross Reference: Listing 16.2.8.2.2

Source: ADEG

Program: xxxx.SAS

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Table 14.3.4.3.4
ECG: Overall Normality Shift from Baseline to the Worst Post-baseline Evaluation - Part A + B
Safety Analysis Set

Shift	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
Normal -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> Abnormal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal -> Missing, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal -> Abnormal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal -> Missing, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Normal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Abnormal, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing -> Missing, n (%)				

Abbreviations: IMP = Investigational Medicinal Product.

Note: Baseline is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on total number of subjects in safety analysis set in each treatment group or Total.

Cross Reference: Listing 16.2.8.2.2

Source: ADEG

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

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Table 14.3.4.4
Physical Examination Results by Visit - Part A + B
Safety Analysis Set

Body System	Visit Assessment	Placebo (N=XX)	ABC008 0.5mg/kg (N=XX)	ABC008 2.0mg/kg (N=XX)	Total (N=XX)
General Appearance	Day 1 (Baseline)	xx	xx	xx	xx
	n	xx	xx	xx	xx
	Normal	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)
	Abnormal - CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Week 48				
	n	xx	xx	xx	xx
	Normal	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)
	Abnormal - CS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for 76					
Repeat for Head, Ears, Eyes, Nose and Throat examination					

Abbreviations: NCS = Not clinically Significant, CS = Clinically Significant

Note: Percentages are based on total number of subjects in safety analysis set in each treatment group or Total.

Note: Only Part A patients had a Week 20 visit per protocol.

Cross Reference: Listing 16.2.8.2.3

Source: ADPE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Table Generation: YYYY-MM-DD:HH:MM

Programming Note:

PE includes appearance, head, ears, eyes, nose, throat, dentition, thyroid, chest (including heart and lungs), abdomen (including liver and spleen), skin, neurological, extremities, back, neck, musculoskeletal, and lymph nodes

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Table 14.3.4.5
Columbia-Suicide Severity Rating Scale (C-SSRS) - Part A + B
Safety Analysis Set

Visit	Placebo (N=XX) n (%)	ABC008 0.5mg/kg (N=XX) n (%)	ABC008 2.0mg/kg (N=XX) n (%)	Total (N=XX) n (%)
Screening, n	xx	xx	xx	xx
Suicidal Ideation in Lifetime, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Wish to be dead, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-specific active suicidal thoughts, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with any methods (not plan) without intent to act, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with some intent to act, without specific plan, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with specific plan and intent, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intensity of Ideation, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicidal Ideation 6 month prior to enrolment, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Wish to be dead, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-specific active suicidal thoughts, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with any methods (not plan) without intent to act, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with some intent to act, without specific plan, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with specific plan and intent, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intensity of Ideation, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicidal Behavior in Lifetime				
Actual Attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Suicidal Self-Injurious Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Interrupted attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Aborted Attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preparatory Acts or Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicidal Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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Suicidal Behavior in past 2 years				
Actual Attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Suicidal Self-Injurious Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Interrupted attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Aborted Attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preparatory Acts or Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicidal Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 1, n	xx	xx	xx	xx
Suicidal Ideation, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Wish to be dead, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-specific active suicidal thoughts, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with any methods (not plan) without intent to act, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with some intent to act, without specific plan, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Active suicidal ideation with specific plan and intent, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Most Severe Ideation, n(%)				
Type 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicidal Behavior				
Actual Attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Suicidal Self-Injurious Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Interrupted attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Avorted Attempt, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preparatory Acts or Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicidal Behavior, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Suicide, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for 16, 24, 48, 76				

Abbreviations: IMP = Investigational Medicinal Product, C-SSRS = Columbia-Suicide Severity Rating Scale.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of IMP (on Day 1).

Note: Percentages are based on the number of participants in safety analysis set at each visit (n).

Cross Reference: Listing 16.2.8.2.6

Source: ADQS

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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ListingListing 16.2.1.1
Subject Disposition - Part A + B
Enrolled Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Analysis Set	Date of Informed Consent/ Randomization	Date of first Injection)/ Last Injection /Treatment duration (days)	Date of Study Completion/ Withdrawal (Study Day) [a]	Complete the Treatment/Reason if no	Complete the Study/Reason if no
xxx-xxx	SS/FAS/PPS/ PKS/PDS	YYYY-MM-DD/YYYY-MM-DD	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	YYYY-MM-DD (xx)	Yes	No/ Adverse event
xxx-xxx	SS/FAS/PPS/ PKS/PDS	YYYY-MM-DD/YYYY-MM-DD	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	YYYY-MM-DD (xx)	Yes	Yes

Abbreviations: ES = Enrolled Set, SS = Safety Analysis Set, FAS = Full Analysis Set, PPS = Per-Protocol Set, PKS = Pharmacokinetics Analysis Set, PDS = Pharmacodynamic Analysis Set.

Note: Treatment duration (days) = date of last injection - date of first injection + 1

[a] If date is on or after first injection date, study day = (date of completion/withdrawal - date of first injection + 1). If date is before first injection date, study day = (date of completion/withdrawal - date of first injection).

Source: ADSL

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

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Listing 16.2.1.2
Subject Disposition - Part C
Subjects Enrolled to Part C

Treatment Group: < Placebo, 0.5mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Analysis Set	Date of Enrolled to Part C	Date of Study Completion/ Withdrawal (Study Day) [a]	Complete the Study/Reason if no
xxx-xxx	PDCS	YYYY-MM-DD	YYYY-MM-DD (xx)	No/ Adverse event
xxx-xxx	PDCS	YYYY-MM-DD	YYYY-MM-DD (xx)	Yes

Abbreviations: PDCS =PD Part C Analysis Set.

[a] study day = (date of completion/withdrawal - date of enrolled to Part C).

Source: ADSL

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

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Listing 16.2.2.1
Protocol Deviations - Part A + B
Enrolled Set

Treatment Group: < Placebo, 0.5mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Start Date (Study Day) / Stop Date (Study Day)	Category for Protocol Deviation	Deviation Classification	Deviation Description	Lead to Exclusion from Analysis Set	Reason for Exclusion from PPS
xxx-xxx	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	Category 1	Important	xxxxxxxxxxxxxxxxxxxxxxxx	FAS	
	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	Category 2	Not important	xxxxxxxxxxxxxxxxxxxxxxxx		
	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	Category 3	Important	xxxxxxxxxxxxxxxxxxxxxxxx	PKS	
	YYYY-MM-DD (xx)					

Abbreviations: SS = Safety Analysis Set, FAS = Full Analysis Set, PPS = Per-Protocol Set, PKS = Pharmacokinetics Analysis Set, PDS = Pharmacodynamic Analysis Set.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Source: ADDV

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

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Listing 16.2.3.1
Subjects Excluded from the Analysis Sets - Part A + B
Enrolled Set

Treatment Group: <Screen Failure, Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Analysis Set	Included	Reason Excluded
xxx-xxx	Safety Analysis Set	Yes	
	Full Analysis Set	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	Full Analysis Set		
	Per-Protocol Analysis Set	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	Pharmacokinetic Analysis Set	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	Pharmacodynamic Analysis Set	Yes	
xxx-xxx	PD Part C Analysis Set	Yes	
	Full Analysis Set	No	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
			

Abbreviations: PD = Pharmacodynamic.

Source: ADSL

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming Note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.4.1
Demographics - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Age (yrs)	Sex/If Female, status of child-bearing potential/post-menopausal?	Race	Ethnicity	Baseline Height (cm)/Weight (kg)	Baseline BMI (kg/m ²)	Alcohol Drinking	Smoking
xxx-xxx	xx	F/Yes	White	xxxxx	xxx/ xx.x	xx.x	No	never smoked
xxx-xxx	xx	F/Yes	White	xxxxx	Xxx/xx.x	xx.x	Yes/ Beer	current smoker

Abbreviations: M = Male, F = Female, yrs = years, BMI = Body mass index.

Note: BMI (kg/m²) is calculated as [weight (kg)] / [height (m)]², rounded to one decimal place.

Source: ADSL

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.4.2
Medical History - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ End Date (Study Day) [a]/ Ongoing	If Ongoing, check if the subject is taking medication for this condition
xxx-xxx	xxxxxxx/ xxxxxxx/ xxxxxxx	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	
xxx-xxx	xxxxxxx/ xxxxxxx/ xxxxxxx	YYYY-MM-DD (xx) / Ongoing	xx
xxx-xxx	xxxxxxx/ xxxxxxx/ xxxxxxx	YYYY-MM-DD (xx) / YYYY-MM-DD (xx)	

Note: Medical history is coded into the Medical Dictionary for Regulatory Activities (MedDRA), version 25.1.

[a] If date is on or after first injection date, study day = (date of medical history - date of first injection + 1). If date is before first dosing date, study day = (date of medical history - date of first injection).

Source: ADMH

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group, then by start date.

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Listing 16.2.4.3
Baseline Disease Characteristics - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Partici pant ID	Age of onset/ diagnosis (yrs)	ENMC Criterion met	Assista nce use	IBMFRS	MMT- 2/ MMT	score	SF-36v2 PCS/MCS	EQ- 5D-5L	mTUG	Grip/quadrice ps strength (kg)	
xxx-xxx	xx.x/xx.x	Clinicopatholog ically defined IBM	Yes	xxx	xx/xx	xxx	xx.x/xx. x	xx.x	xx	xx/xx	xx/xxxx
xxx-xxx	xx.x/xx.x	Clinically defined IBM	No	xxx	xx/xx	xxx	xx.x/xx. x	xx.x	xx	xx/xx	xxx/xxx
xxx-xxx	xx.x/xx.x	Probably IBM	Yes	xxx	xx/xx xx/xx	xxx	xx.x/xx. x	xx.x	xx	xx/xx	xxx/xxx

Abbreviations: ENMC = European Neuromuscular Centre, IBMFRS = IBM Functional Rating Scale, MMT = Manual Muscle Testing, SF-36v2 = Short Form 36-item Health Survey Version 2, PCS = Physical component summary, MCS = Mental component summary, EQ-5D-5L = EuroQol-5 Dimensional, mTUG = Modified Timed Up and Go.

Source: ADSL

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.4.4
Prior and Concomitant Medications - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	ATC Level 4/ Preferred Term / Verbatim Name	Prior or Concomitant	Start Date (Study Day) / Stop Date (Study Day) / Ongoing	Dose (Units) / Route / Frequency /	Indication
xxx-xxx	XXXXXX/ XXXXXX/ XXXXXX	Prior	YYYY-MM-DD (xxx) / YYYY-MM-DD (xxx)	XXXXXXX (Other:xxxx) / XXXXXX/ XXXXXX/	XXXXXXX
xxx-xxx	XXXXXX/ XXXXXX/ XXXXXX	Concomitant	YYYY-MM-DD (xxx) / Ongoing	XXXXXXX (Other:xxxx) / XXXXXX/ XXXXXX/	XXXXXXX
xxx-xxx					

Abbreviations: WHO = World Health Organization.

Note: Prior and Concomitant Medication is coded with WHO Drug Dictionary (WHO-DD) version global B3, Sept 2022

Note: If date is on or after first Injection date, study day = (date of medical history - date of first injection + 1). If date is before first dosing date, study day = (date of medical history - date of first injection).

Source: ADCM

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programmer note:

Order by treatment groups shown. Sort by Participant ID within each treatment group, then by therapy start date.

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Listing 16.2.5.1
Study Drug Administration - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Partici pant ID	Visit	Study Drug Administered	Date and Time of Administration (Study Day)	Location of injection/ # of injections	volume of injections (mL)	Study Drug Given per Protocol
xxx-xxx	Day 1	Yes	YYYY-MM-DDTHH:MM (xx)	Left Anterior Thigh/xx Left Lower Abdominal Cavity /xx	xx.x xx.x	Yes
	USV	Yes	YYYY-MM-DDTHH:MM (xx)	Left Upper Abdominal Cavity/xx Left anterior thigh/xx	xx.x xx.x	No: xxx
	Week 24	No: xxxxx				

Abbreviations: USV = Unscheduled Visit.

Note: If date is on or after the date of first dose, study day = (date of administration - date of first dose + 1). If date is before the date of first dose, study day = (date of administration - date of first dose).

Source: ADEX

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming Notes:

1. Order by treatment groups shown. Sort by Participant ID within each treatment group, then by therapy start date. location of injection (Subjects may have multiple injection sites per visit)
2. If Study Drug was not administered, append the reason.
3. If study drug was not given per protocol, append the reason.

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Listing 16.2.5.2
Study Drug Compliance - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Duration of treatment (Weeks)	Total # of injections/ # of injections missed	Total volume of injections (mL)/ Expected total volume of injections (mL)	Overall Treatment Compliance (%)
xxx-xxx	xxx	xx/xx	xxx.x/xxx.x	xx.xx

Source: ADEXSUM
Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming Notes:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.6.1
Inclusion Body Myositis Functional Rating Scale (IBMFRS) - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed (Reason if No)	Assessment Date (Day)	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q9	Q10	Total Score
xxx-xxx	Screening	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Day 1	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Week 8	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Week 16	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	USV	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Week 32	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Week 64	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	Week 76	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
	EOT/ETV	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

xxx-xxx

Abbreviations: EOT = End-of-Treatment, ETV = Early Termination Visit, USV = Unscheduled Visit, IBMFRS = Inclusion Body Myositis Functional Rating Scale, Q = Question.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Note: Total IBMFRS score is the sum of score of all items, the higher the score the better the functional status of the patient.

Source: ADFT

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date within each treatment group.

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Listing 16.2.6.2
Manual Muscle Testing - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed (Reason if No)	Assessment Date (Day)	Test Item	Test Score Left/Right	MMT score	MMT12 score
xxx-xxx	Screening	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx	xx	xx
				Elbow Flexors	xx/xx		
				Wrist Flexors	xx/xx		
				Wrist Extensors	xx/xx		
				Flexor Pollicis Longus	xx/xx		
				Hip Flexors	xx/xx		
				Knee Extensors	xx/xx		
				Ankle Dorsiflexors	xx		
				Neck Flexors	xx/xx		
				Elbow Extensors	xx/xx		
				Hip Abductors	xx/xx		
				Hip Extensors	xx/xx		
	Day 1	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	Week 8	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	Week 16	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	USV	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	Week 32	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	Week 64	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	Week 76	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		
	EOT/ETV	Yes	YYYY-MM-DD (xx)	Shoulder Abductors	xx/xx		

Abbreviations: EOT = End-of-Treatment, ETV = Early Termination Visit, USV = Unscheduled Visit, MMT = Manual Muscle Testing.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Source: ADMK

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date within each treatment group.

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Listing 16.2.6.3
Dynamometry - Grip Strength - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID/Dominate hand	Visit	Assessment Performed (Reason, if No)	Assessment Date (Day)	Right Hand Grip Strength (kg)				Left Hand Grip Strength (kg)			
				1	2	3	Average	1	2	3	Average
xxx-xxx/Left	Screening	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 1	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 8	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 16	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	USV	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 32	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 64	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 76	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	EOT/ETV	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Abbreviations: EOT = End-of-Treatment, ETV = Early Termination visit, UNK = Unknown, USV = Unscheduled Visit, ND = Not Done.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Source: ADMK

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date within each treatment group.

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Listing 16.2.6.4
Dynamometry - Quadriceps Strength - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID/ Dominate Leg	Visit	Assessment Performed (Reason if No)	Assessment Date (Day)	Right Leg Quadriceps Strength (kg)				Left Leg Quadriceps Strength (kg)			
				1	2	3	Average	1	2	3	Average
xxx- xxx/Left	Screening	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Day 1	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 8	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 16	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	USV	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 32	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 64	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Week 76	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	EOT/ETV	Yes	YYYY-MM-DD (xx)	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Abbreviations: EOT = End-of-Treatment, ETV = Early Termination visit, UNK = Unknown, USV = Unscheduled Visit, ND = Not Done.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Source: ADMK

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date and date within each treatment group.

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Listing 16.2.6.5
Modified Timed Up and Go (mTUG) Test - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed (Reason if No)	Assessment Date (Day)	Result (second)	Aids Used
xxx-xxx	Screening	Yes	YYYY-MM-DD (xx)	xx	1-Independent (walking without any walking aids or assistance)
	Day 1	Yes	YYYY-MM-DD (xx)	xx	2 - Cane/crutch/rail
	Week 8	Yes	YYYY-MM-DD (xx)	xx	3 - Canes/crutches/rails
	Week 16	Yes	YYYY-MM-DD (xx)	xx	4 - Walker (standard walker or 2- or 4- wheeled walker)
	Week 32	Yes	YYYY-MM-DD (xx)	xx	
	USV	Yes	YYYY-MM-DD (xx)	xx	
	Week 64	Yes	YYYY-MM-DD (xx)	xx	5 - Unable to complete
	Week 76	Yes	YYYY-MM-DD (xx)	xx	
	EOT/ETV	Yes	YYYY-MM-DD (xx)	xx	

Abbreviations: EOT = End-of-Treatment, ETV = Early Termination visit, USV = Unscheduled Visit.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Source: ADFT

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date within each treatment group.

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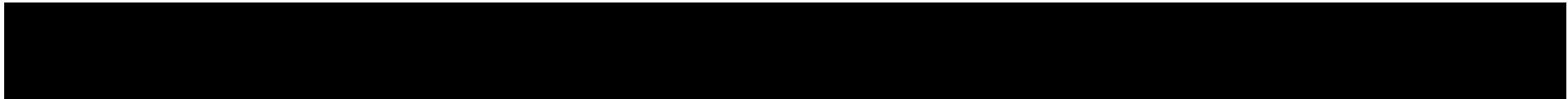
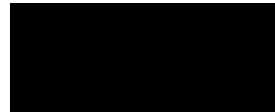
Statistical Analysis Plan for Interventional Studies

Sponsor: Abcuro Inc; Protocol No.: ABC008-IBM-201

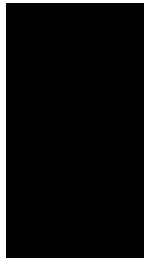
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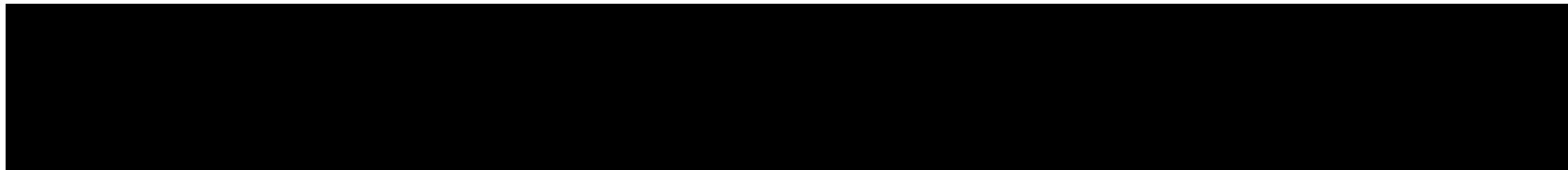
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Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

Program: xxxx.SAS
DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date within each treatment group.

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Program: xxxx.SAS

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Listing 16.2.6.9
SF-36v2 - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed	Assessment Date (Day)	Questionnaire	Result/Score
xxx-xxx	Screening	Yes	YYYY-MM-DD (xx)	Q1	x
				Q2	x
				...	
				Q11d	x
				Physical Functioning	
				...	
				PCS	xx.x
				MCS	xx.x
	Day 1	Yes	YYYY-MM-DD (xx)	x	x
	Week 8	Yes	YYYY-MM-DD (xx)	x	x
	Week 16	Yes	YYYY-MM-DD (xx)	x	x
	USV	Yes	YYYY-MM-DD (xx)	x	x
	Week 32	Yes	YYYY-MM-DD (xx)	x	x
	Week 64	Yes	YYYY-MM-DD (xx)	x	x
	Week 76	Yes	YYYY-MM-DD (xx)	x	x
	EOT/ETV	Yes	YYYY-MM-DD (xx)	x	x

Abbreviations: USV = Unscheduled Visit.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Source: ADQS

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID and assessment date within each treatment group.

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Listing 16.2.6.10
EuroQol 5-dimension 5-level Quality of Life (EQ-5D-5L)- Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed (Reason if No)	Assessment Date (Day)	Mobility	Self-Care	Usual Activities	Pain/ Discomfort	Anxiety/ Depression	VAS score
xxx-xxx	Screening	Yes	YYYY-MM-DD (xx)	1	2	3	4	5	xx
	Day 1	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	Week 8	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	Week 16	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	USV	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	Week 32	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	Week 64	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	Week 76	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx
	EOT/ETV	Yes	YYYY-MM-DD (xx)	xx	xx	xx	xx	xx	xx

Abbreviations: EQ-5D-5L = EuroQol 5 Dimension 5 Level Quality-of-Life Questionnaire, VAS = Visual analogue scale, EOT = End-of-Treatment, ETV = Early Termination Visit, USV = Unscheduled Visit.

Note: If date is on or after the date of first dose, study day = (date of assessment - date of first dose + 1). If date is before the date of first dose, study day = (date of assessment - date of first dose).

Note: EQ-5D-5L score: 1 = No problems, 2 = Slight problems, 3 = Moderate problems, 4 = Severe problems, 5 = Extreme problems. VAS score ranges from 0 to 100, 100 means the best health and 0 means the worst health.

Source: ADQS

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID then Assessment Date and date within each treatment group.

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xxx-xxx

YYYY-MM-DD (xx)

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Program: xxxx.SAS
DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

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Listing 16.2.6.12
Exit Survey (Clinical Trial Experience) - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed (Reason if No)	Assessment Date (Day)	Questionnaire	Result/Score
xxx-xxx	Day 76	Yes	YYYY-MM-DD (xx)	Q1	x
	..			Q2	x
	..			...	
xxx-xxx	Day 76	Yes	YYYY-MM-DD (xx)	Q5	x
				x	x
				x	x
				x	x
xxx-xxx	Day 76	Yes	YYYY-MM-DD (xx)	x	x
				x	x
				x	x
				x	x

Programming note:

Order by treatment groups shown. Sort by Participant ID and assessment date within each treatment group.

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Listing 16.2.7.1.1
Adverse Events - Part A + B
Safety Analysis Set

Treatment: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	System Organ Class/ Preferred Term/ Verbatim Term	Onset Date and Time (Study Day [a])/ End Date and Time (Study Day)	TEAE	SAE /SAE Type [b]	AESI	S: Severity [c] R: Relation to Study Drug	A: Action Taken to Drug [d] OA: Other Action Taken [e] O: Outcome [f]
xxx-xxx	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	YYYY-MM-DDTHH:MM (xxx) / YYYY-MM-DDTHH:MM (xxx) /xxx	Yes	No	No	S:2 R:Not related	A:1 OA:1 O:1
xxx-xxx	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	YYYY-MM-DDTHH:MM (xxx) / YYYY-MM-DDTHH:MM (xxx) /xxx	Yes	Yes/1	No	S:2 R:Not related	A:1 OA:1 O:1

Abbreviations: AESI = Adverse Events of Special Interest, CTCAE = Common Terminology Criteria for Adverse Events,

IMP = Investigational Medicinal Product, SAE = Serious Adverse Event,

TEAE = Treatment-Emergent Adverse Event.

Note: TEAE is defined as an AE that first appears or worsens after initiation of study drug. Adverse events are coded using MedDRA version 25.1.

[a] Study Day is relative to the first dose of IMP (Day 1). Missing or partial date will not be imputed.

[b] 1 = Life-threatening, 2 = Requires inpatient hospitalization or prolongation of existing hospitalization, 3 = Results in persistent

or significant disability/incapacity, 4 = Congenital anomaly/birth defect, 5 = Important medical event that may jeopardize the participant or may require medical intervention to prevent one of the outcomes listed.

[c] Severity is graded using CTCAE V5.0: 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening, 5 = Death.

[d] Action taken: 1 = Dose not changed, 2 = Dose reduced, 3 = Drug withdrawn, 4 = Dose Increased, 5 = Not applicable, 6 = Unknown

[e] Other action taken: 1 = None, 2 = Concomitant medication, 3 = Other.

[f] Outcome: 1= Recovered/Resolved, 2 = Recovering/Resolving, 3 = Recovered/Resolved with Sequelae, 4 = Not recovered/Not resolved, 5 = Fatal, 6 = Unknown.

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.7.1.2
Adverse Events - Part C
Safety Analysis Set

Repeat Listing 16.2.7.1.1 for AE in part C

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Listing 16.2.7.2.1
Serious Adverse Events - Part A + B
Safety Analysis Set

Treatment: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	System Organ Class/ Preferred Term/ Verbatim Term	Onset Date and Time (Study Day [a])/ End Date and Time (Study Day)/Duration (Day)	TEAE	SAE Type [b]	AESI	S: Severity [c] R: Relation to Study Drug	A: Action Taken to Drug [d] OA: Other Action Taken [e] O: Outcome [f]
xxx-xxx	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	YYYY-MM-DDTHH:MM (xxx) / YYYY-MM-DDTHH:MM (xxx) /xxx	Yes	No	No	S:2 R:Not related	A:1 OA:1 O:1
xxx-xxx	xxxxxxxxxx/ xxxxxxxxxx/ xxxxxxxxxx	YYYY-MM-DDTHH:MM (xxx) / YYYY-MM-DDTHH:MM (xxx) /xxx	Yes	Yes/1	No	S:2 R:Not related	A:1 OA:1 O:1

Abbreviations: AESI = Adverse Events of Special Interest, CTCAE = Common Terminology Criteria for Adverse Events,

IMP = Investigational Medicinal Product, SAE = Serious Adverse Event,

TEAE = Treatment-Emergent Adverse Event.

Note: TEAE is defined as an AE that first appears or worsens after initiation of study drug. Adverse events are coded using MedDRA version 25.1.

[a] Study Day is relative to the first dose of IMP (Day 1). Missing or partial date will not be imputed.

[b] 1 = Life-threatening, 2 = Requires inpatient hospitalization or prolongation of existing hospitalization, 3 = Results in persistent

or significant disability/incapacity, 4= Congenital anomaly/birth defect, 5 = Important medical event that may jeopardize the participant or may require medical intervention to prevent one of the outcomes listed.

[c] Severity is graded using CTCAE V5.0: 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening, 5 = Death.

[d] Action taken: 1 = Dose not changed, 2 = Dose reduced, 3 = Drug withdrawn, 4 = Dose Increased, 5 = Not applicable, 6 = Unknown

[e] Other action taken: 1 = None, 2 = Concomitant medication, 3 = Other.

[f] Outcome: 1= Recovered/Resolved, 2 = Recovering/Resolving, 3 = Recovered/Resolved with Sequelae, 4 = Not recovered/Not resolved, 5 = Fatal, 6 = Unknown.

Listing 16.2.7.2.2
Serious Adverse Events - Part C
Safety Analysis Set

Repeat Listing 16.2.7.2.1 for Serious Adverse Events in Part C

This document is confidential.

Listing 16.2.7.3.1
Adverse Events of Special Interest - Part A + B
Safety Analysis Set

Repeat Listing 16.2.7.1.1 for Adverse Events of Special Interest

Footnote:

Abbreviations: AESI = Adverse Events of Special Interest, CTCAE = Common Terminology Criteria for Adverse Events, IMP = Investigational Medicinal Product, SAE = Serious Adverse Event, TEAE = Treatment-Emergent Adverse Event.
Note: TEAE is defined as an AE that first appears or worsens after initiation of study drug. Adverse events are coded using MedDRA version 25.1.

[a] Study Day is relative to the first dose of IMP (Day 1). Missing or partial date will not be imputed.

[b] 1 = Life-threatening, 2 = Requires inpatient hospitalization or prolongation of existing hospitalization, 3 = Results in persistent

or significant disability/incapacity, 4 = Congenital anomaly/birth defect, 5 = Important medical event that may jeopardize the participant or may require medical intervention to prevent one of the outcomes listed.

[c] Severity is graded using CTCAE V5.0: 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening, 5 = Death

[d] Action taken: 1 = Dose not changed, 2 = Dose reduced, 3 = Drug withdrawn, 4 = Dose Increased, 5 = Not applicable, 6 = Unknown

[e] Other action taken: 1 = None, 2 = Concomitant medication, 3 = Other

[f] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Recovered/Resolved with Sequelae, 4 = Not recovered/Not resolved, 5 = Fatal, 6 = Unknown

Source: ADAE

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Listing 16.2.7.3.2
Adverse Events of Special Interest - Part C
Safety Analysis Set

Repeat Listing 16.2.7.3.1 for Adverse Events of Special Interest in Part C

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Listing 16.2.7.4.1
Deaths - Part A + B
Safety Analysis Set

Treatment: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Death Date (Day)	Primary Cause of Death
xxx-xxx	YYYY-MM-DD(xx)	xxxxxxxxxxxxxxxxxxxxxx
xxx-xxx	YYYY-MM-DD(xx)	xxxxxxxxxxxxxxxxxxxxxx

Abbreviations: IMP = Investigational Medicinal Product.

Note: Study Day is relative to the first dose of IMP (Day 1). Missing or partial date will not be imputed.

Source: ADSL

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Listing 16.2.7.4.2
Deaths - Part C
Safety Analysis Set

Repeat Listing 16.2.7.4.1 for Deaths in Part C

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Listing 16.2.8.1.2
Hematology - Part A + B
Safety Analysis Set

Treatment: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Age (yrs)/Sex/Region	Visit	Date of Assessment (Study Day)	Parameter (Unit)	Result	Normal Range
xxx-xxx	35/F/Europe	Screening	YYYY-MM-DD (xx)	basophils (xx)	xxx (L)	xxx-xxx
				eosinophils (xx)	xxx (L)	xxx-xxx
				lymphocytes (xx)	xxx (L)	xxx-xxx
				etc.		
		Day 1	Not Done, xxxxx			
.....						

Abbreviations: yrs = years, M = Male, F = Female, H = High, L = Low, USV = Unscheduled Visit.

Note: Results outside of the normal range are flagged as low (L) or high (H).

Source: ADLB

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Parameter Include basophils, eosinophils, lymphocytes, monocytes, neutrophils), platelet count, percent and absolute CD4+ count, percent and absolute CD8+ count, and CD4:CD8 ratio. Percent and absolute CD3+, CD19+ (B cell), and CD16/56+ (NK cell) counts

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Listing 16.2.8.1.2C
Hematology in Conventional Units - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Hematology in conventional units

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Parameter Include basophils, eosinophils, lymphocytes, monocytes, neutrophils), platelet count, percent and absolute CD4+ count, percent and absolute CD8+ count, and CD4:CD8 ratio. Percent and absolute CD3+, CD19+ (B cell), and CD16/56+ (NK cell) counts

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Listing 16.2.8.1.3
Blood Chemistry - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Blood Chemistry

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Blood Chemistry parameters include albumin, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, C reactive protein, calcium, creatinine, gamma-glutamyl transpeptidase, glucose, lactate dehydrogenase, potassium, sodium chloride, total bilirubin, total protein, uric acid. eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation

Listing 16.2.8.1.3C
Blood Chemistry in Conventional Units - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Blood Chemistry in conventional units

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Blood Chemistry parameters include albumin, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, C reactive protein, calcium, creatinine, gamma-glutamyl transpeptidase, glucose, lactate dehydrogenase, potassium, sodium chloride, total bilirubin, total protein, uric acid. eGFR will be calculated by the Chronic Kidney Disease Epidemiology Collaboration equation

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Listing 16.2.8.1.4
Urinalysis - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Urinalysis

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Urinalysis parameters include Color, appearance, specific gravity, pH, protein, glucose, ketones, bilirubin, blood, urobilinogen, nitrite, leukocyte

This document is confidential.

Listing 16.2.8.1.4C
Urinalysis in Conventional Units - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Urinalysis in conventional units

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Urinalysis parameters include Color, appearance, specific gravity, pH, protein, glucose, ketones, bilirubin, blood, urobilinogen, nitrite, leukocyte

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Listing 16.2.8.1.5
Complement Test - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Complement test: C3, C4, and CH50

Listing 16.2.8.1.5C
Complement Test in Conventional Units - Part A + B
Safety Analysis Set

Repeat Listing 16.2.8.1.2 for Complement test: C3, C4, and CH50 in conventional units

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

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Listing 16.2.8.1.6
T4 and TSH - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Age (yrs)/Sex/Region	Visit	Date of Assessment (Study Day)	Was Test Performed (Reason if no)	T4		TSH	
					Result	Normal Range	Result	Normal Range
xxx-xxx	35/F/Europe	Screening	YYYY-MM-DD (xx)	Yes	xx.x (L)	xx.x-xx.x	xx.xx	xx.xx-xx.xx
		Week 16	YYYY-MM-DD (xx)	Yes	xx.x	xx.x-xx.x	xx.xx	xx.xx-xx.xx
		Week 76	YYYY-MM-DD (xx)	Yes	xx.x	xx.x-xx.x	xx.xx	xx.xx-xx.xx

Abbreviations: yrs = years, M = Male, F = Female, TSH = thyroid stimulating hormone H = High, L = Low, USV = Unscheduled Visit., H = High, L = Low, USV = Unscheduled Visit.

Note: Results outside of the normal range are flagged as low (L) or high (H).

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Listing 16.2.8.1.6C
T4 and TSH in Conventional Units - Part A + B
Safety Analysis Set**Repeat Listing 16.2.8.1.6 in conventional units**

Source: ADLC

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing
CD3 and CD4 T Lymphocyte [REDACTED] - Part A + B
Pharmacodynamic Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Analyte: XXXX (Unit)

Participant ID	Cohort	Visit	Was Test Performed (Reason if no)	Date of Assessment (Study Day)	Result
xxx-xxx	Part A	Screening Day 1	Yes	YYYY-MM-DD (xx)	xx
			Yes	YYYY-MM-DD (xx)	xx
			Yes	YYYY-MM-DD (xx)	xx
			Yes	YYYY-MM-DD (xx)	xx
			Yes	YYYY-MM-DD (xx)	xx
		Week 32	Yes	YYYY-MM-DD (xx)	xx
		Week 76	Yes	YYYY-MM-DD (xx)	xx

Note: Participants in Part B will have additional timepoints reported compared to Part A.

Source: ADLB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups and analyte shown. Sort by [REDACTED] within each treatment and analyte group. This table should list all the CD3 and CD4 T cell analytes of the [REDACTED] assays (A167 and A942). See comment on color coding of analytes in excel file "Flow Assay A167 A942 Reportables October 18 2025" and common description of each analyte

Listing 16.2.8.1.7.1b
CD8 T Lymphocyte [REDACTED] - Part A + B
Pharmacodynamic Analysis Set

Repeat Listing 16.2.8.1.7.1a**Programming note:**

Order by treatment groups and analyte shown. Sort by Participant ID within each treatment group. This table should list all the CD8 T cell analytes of the [REDACTED] assays (A167 and A942). See comment on color coding of analytes in excel file "Flow Assay A167 A942 Reportables October 18 2025" and common description of each analyte

Listing
NK/NKT Lymphocyte [REDACTED] - Part A + B
Pharmacodynamic Analysis Set

Repeat Listing 16.2.8.1.7.1a**Programming note:**

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Order by [REDACTED]s shown. Sort by Participant ID within each treatment group. This table should list all NK / NKT analytes of the [REDACTED] assays (A167 and A942). See comment on color coding of analytes in excel file "Flow Assay A167 A942 Reportables October 18 2025" and common description of each analyte

Listing 16.2.8.1.7.1d
B Lymphocyte and CD14+ [REDACTED] - Part A + B
Pharmacodynamic Analysis Set

Repeat Listing 16.2.8.1.7.1a

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group. This table should list all B lymphocyte and CD14+ cells of the [REDACTED] assays (A167 and A942). See comment on color coding of analytes in excel file "Flow Assay A167 A942 Reportables October 18 2025" and common description of each analyte

Listing 16.2.8.1.7.2
All Lymphocytes - Part C
Pharmacodynamic Analysis Set

Repeat Listing 16.2.8.1.7.1a-d for Part C data. Make sure to include all parameters from all four listings

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Listing 16.2.8.1.8
Tuberculosis Test - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID/	Visit	Date of Test (Study Day)	Was Test Performed (Reason if no)	Test Method	Result	Clinical interpretation
xxx-xxx	Screening	YYYY-MM-DD(xx)	Yes	QuantiFERON-TB Gold Plus	Negative	Normal
xxx-xxx	Screening	YYYY-MM-DD(xx)	Yes	QuantiFERON-TB Gold Plus	Normal	Abnormal - NCS
xxx-xxx	Screening	YYYY-MM-DD(xx)	Yes	T.SPOT-TB	Positive	Abnormal - CS

Abbreviations: NCS = Not clinically significant, CS = Clinically significant.

Source: ADMB

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.8.1.9
Pregnancy Test - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Date of Test (Study Day)	Test	Test Type	Result
xxx-xxx	Screening	YYYY-MM-DD(xx)	HCG	Urine	Negative
xxx-xxx	Screening	YYYY-MM-DD(xx)	HCG	Serum	Negative
xxx-xxx	Screening	YYYY-MM-DD(xx)	HCG	Positive	Negative

Abbreviations: USV = Unscheduled Visit.

Source: ADLB

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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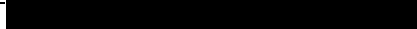
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Listing 16.2.8.1.10
COVID-19 Test- Part A + B
Safety Analysis Set

Treatment: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Date of Test (Study Day)	Was Test Performed (Reason if no)	Test Method	Result
xxx-xxx	Screening Day 1	YYYY-MM-DD (xx)	Yes	 Rapid antigen test (L)	N Negative

Abbreviations:  USV = Unscheduled Visit.

Note: Results outside of the normal range are flagged as low (L) or high (H).

Source: SDTM.MB

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.8.1.11
Viral Serology Test- Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Date of Test (Study Day)	HBV	HCV	HIV-1	HIV-2	CMV	EBV	HSV-1	HSV-2	VZV
xxx-xxx	Screening	YYYY-MM-DD (xx)	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
	Week 76	YYYY-MM-DD (xx)	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative

Source: SDTM.MB

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

Viral Serology tests include: HIV-1 and -2, HBV core antibody and surface antigen, and HCV antibody with reflex HCV RNA, and herpes viruses such as EBV, CMV, HSV-1 and -2, and VZV.

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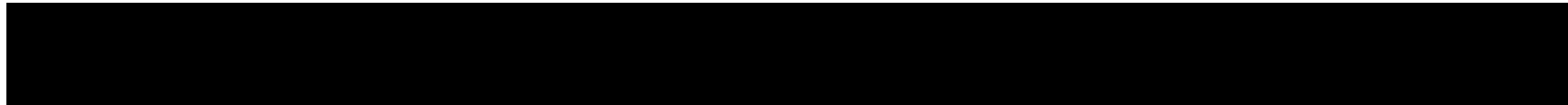
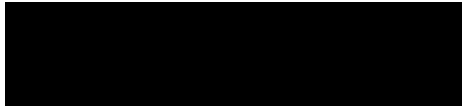
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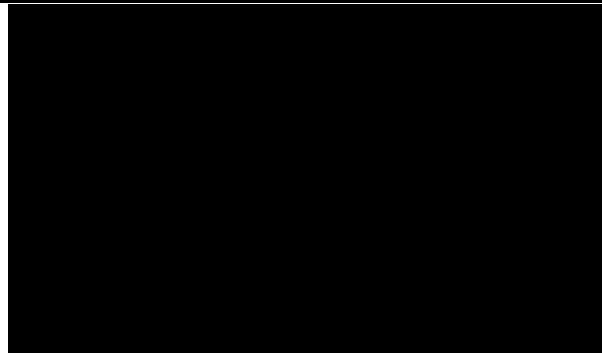


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YYYY-MM-DD (xx)

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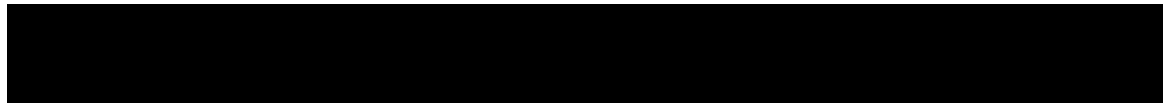
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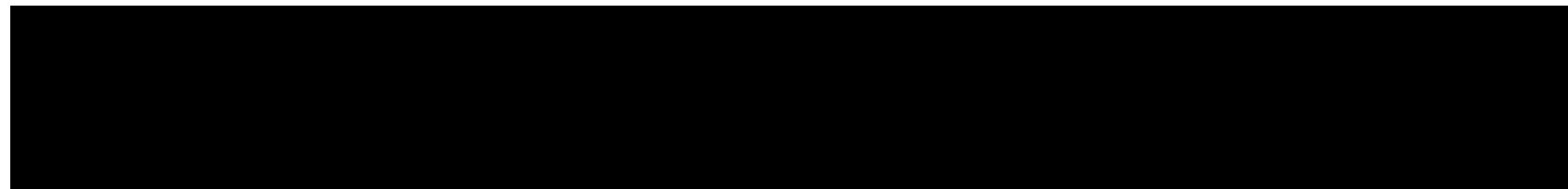
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Program: xxxx.SAS
DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-



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Listing 16.2.8.2.1
Vital Signs - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Was Assessment Performed (Reason if no)	Assessment Date (Study Day)	SBP (mmHg)/DBP (mmHg)	Pulse Rate (beats/min)	Respiratory Rate (breaths/min)	Temperature (°C)	Overall Assessment
xxx-xxx	Screening	Yes	YYYY-MM-DD (xxx)	xxx/xxx	xxx	xxx	x.xx	Normal
	Day 1	Yes	YYYY-MM-DD (xxx)	xxx/xxx	xxx	xxx	x.xx	Abnormal - NCS
	Week 1, 2,							
	4, 8, 12,							
	16, 20,							
	24, 32,							
	40, 48,							
	56, 64, 72,							
	76							
...								

Abbreviations: SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure, CS = Clinically Significant, NCS= Not clinically significant, USV = Unscheduled Visit.

Note: If date is on or after first dosing date, study day = (date of assessment - date of first dose + 1). If date is before first dosing date, study day = (date of assessment - date of first dose).

Note: All temperature units were standardized to Celcius.

Source: ADVS

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-DD:HH:MM

Programming note:

Week 20 results are only expected for Part A subjects.

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Listing 16.2.8.2.2
12-Lead Electrocardiogram - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Timepoint	Assessment Date/Time (Study Day)	Heart Rate (bpm) [a]	RR (msec)	PR (msec) [b]	QRS (msec) [c]	QT (msec)	QTcF (msec) [d]	Interpretation [e]
XXX-XXX	Screening	1	YYYY-MM-DD (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	Normal
		2	YYYY-MM-DD (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	Abnormal*
		3	YYYY-MM-DD (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	Abnormal
		Average		xxx	xxx	xxx	xxx	xxx	xxx	
	Week 16	1		xxx	xxx	xxx	xxx	xxx	xxx	Normal
		2		xxx	xxx	xxx	xxx	xxx	xxx	Abnormal
		3		xxx	xxx	xxx	xxx	xxx	xxx	Abnormal
		Average/CHG		xxx/xxx [*]	xxx/xxx	xxx/xxx *	xxx/xxx *	xxx/xxx	xxx*/xxx +	

Abbreviations: bpm = beats per minute, msec = milliseconds, CHG = change from baseline, USV = Unscheduled Visit, F = Female, M = Male.

Study Day = Assessment Date - Date of First Dose of Study Medication + 1

QTcF is calculated using Fridericia's formula: $QTcF = QT / (RR)^{1/3}$ in case QTcF is not available in ECG data.

[a] * = Decrease from Baseline > 25% and HR < 50; + = Increase from Baseline > 25% and HR > 100

[b] * = Increase from Baseline > 25% and PR > 200

[c] * = Increase from Baseline > 25% and QRS > 100

[d] * = ≤ 450 (M), ≤ 470 (F); ** = > 450 (M), > 470 (F); *** = > 500; + = Increase from Baseline > 30; ++ = Increase from Baseline > 30 to ≤ 60; +++ = Increase from Baseline > 60.

[e] * = first worst overall interpretation.

Source: ADEG

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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Listing 16.2.8.2.3
Physical Examination - Part A + B
Safety Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID/Age/Sex	Visit	Was Physical Examination Performed?	Date of Examination	Body System	Result	If abnormal, specify
		Reason if no	(Study Day)			
XXXXXX/XXX/X	xxxx	Yes	YYYY-MM-DD(xx)	General Appearance	Abnormal, CS	xxxxxxxxxx
				Eye, Ear, Nose and Throat	Normal	
				Head and Neck		
				Respiratory		
						

Abbreviations: CS = Clinically Significant, NCS = Not Clinically Significant, USV = Unscheduled Visit.

Note: If date is on or after first dosing date, study day = (date of examination - date of first dose + 1). If date is before first dosing date, study day = (date of examination - date of first dose).

Source: ADPE

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Sort the listing by treatment, then Participant ID. Then within the same subject, sort by visit and examination date and body system. Order body system in alphabetical order.

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[REDACTED]

XXX-XXX

[REDACTED]

YYYY-MM-DD (xxx)

xxx

YYYY-MM-DD (xxx)

xxxx

YYYY-MM-DD (xxx)

xxxx

YYYY-MM-DD (xxx)

xxxx

[REDACTED]

Program: xxxx.SAS

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Program: xxxx.SAS
DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Listing 16.2.8.2.5
Immunoglobulins - Part A + B
Pharmacodynamic Analysis Set

Repeat Listing 16.2.8.1.5 for Serum Immunoglobulins

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.
Serum Immunoglobulins include immunoglobulins, M protein, and light chain ratio

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Listing 16.2.8.2.6

Suicidal Ideation, Suicidal Behavior and Non-suicidal Self-Injurious Behavior Based on C-SSRS - Part A + B
Full Analysis Set

Treatment Group: < Placebo, 0.5 mg/kg ABC008, 2.0 mg/kg ABC008>

Participant ID	Visit	Assessment Performed (Reason,if No)	Assessment Date/(Day) [a]	Suicidal Ideation [b]						Suicidal Behavior [c]						
				1	2	3	4	5	6	7	8	9	10	11	12	13
xxx-xxx	Screening															
	Lifetime	Yes	YYYY-MM-DD (xx)	Y	Y	Y	Y	Y	1	Y	Y	Y	Y	Y	Y	
	Past 6 month/2 years			Y	Y	Y	Y	Y	1	Y	Y	Y	Y	Y	Y	
	Day 1 (Baseline)	Yes	YYYY-MM-DD (xx)	Y	Y	Y	Y	Y	1	Y	Y	Y	Y	Y	Y	Y
	Week 8	Yes	YYYY-MM-DD (xx)	N	N	N	Y	N	1	N	N	N	N	Y	Y	N
	Week 16	Yes	YYYY-MM-DD (xx)	N	N	N	Y	N	1	N	N	N	N	Y	Y	N
	Week 24	Yes	YYYY-MM-DD (xx)	N	N	N	Y	N	1	N	N	N	N	Y	Y	N
	Week 48	Yes	YYYY-MM-DD (xx)	N	N	N	Y	N	1	N	N	N	N	Y	Y	N
	Week 76	Yes	YYYY-MM-DD (xx)	N	N	N	Y	N	1	N	N	N	N	Y	Y	N

Abbreviations: C-SSRS = Columbia-Suicide Severity Rating Scale, Y = Yes, N = No.

[a] If date is on or after first dosing date, study day = (date sample was collected - date of first dose + 1). If date is before first dosing date, study day = (date sample was collected - date of first dose).

[b] 1= Wish to be Dead, 2 = Non-specific Active Suicidal Thoughts, 3= Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act, 4 = Active Suicidal Ideation with Some Intent to Act, without Specific Plan, 5 = Active Suicidal Ideation with Specific Plan and Intent, 6 = Most Severe Ideation Type

[c] 7 = Actual Attempt, 8= Non-Suicidal Self-Injurious Behavior, 9 = Interrupted Attempt, 10 = Aborted Attempt, 11 = Preparatory Acts or Behavior, 12 =Suicidal Behavior, 13 = Suicide.

Source: ADQS

Program: xxxx.SAS

DD:HH:MM

Date cut-off:YYYY-MM-DD

Listing Generation: YYYY-MM-

Programming note:

Order by treatment groups shown. Sort by Participant ID within each treatment group.

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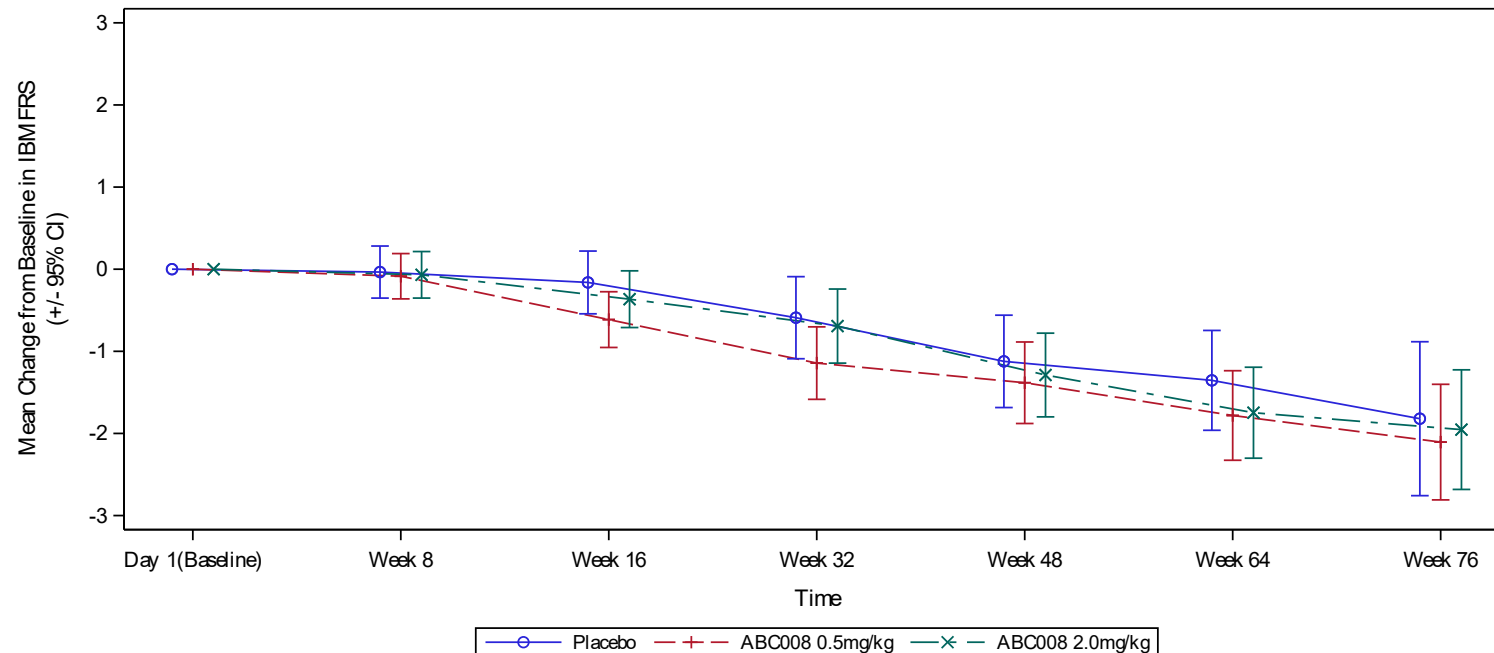
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Figures

Figure 14.2.1.1.2
Change from Baseline in IBMFRS Total Score Over Time - Part A + B
Full Analysis Set



Abbreviations: IBMFRS = Inclusion Body Myositis Functional Rating Scale, CI = Confidence Interval.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of Investigational Medicinal Product (on Day 1).

Note: Missing IBMFRS scores were imputed using multiple imputation as described in Statistical Analysis Plan section 11.1.1.

Note: The change from Baseline in IBMFRS is analyzed using a mixed model repeated measures (MMRM) with unstructured covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Table 14.2.1.1.2, Listing 16.2.6.1

Source: xxx

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PROGRAMMING NOTE:

1. Graph type: Mean Change of IBMFRS Total Score vs study week for each treatment group (Placebo vs ABC008 0.5mg/kg vs ABC008 2.0mg/kg), adding error bar for 95%CI , Graph needs to use symbols/line styles which are easily distinguishable when the graph is printed in black and white.
2. x-axis label: Time;
3. x-axis scale: day 1, week 8, 16, 32, 48, 64, 76
4. y-axis label: Mean Change from Baseline in IBMFRS (+/- 95% CI)
5. y-axis scale: -5 to 5 , in step of 0.1
6. Legend : Treatment Groups (Placebo vs ABC008 0.5mg/kg vs ABC008 2.0mg/kg)

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Figure 14.2.2.1.2
Change from Baseline in MMT-12 Score Over Time - Part A + B
Full Analysis Set

Repeat Figure 14.2.1.1.2 for MMT-12 Score,

Abbreviations: MMT = Manual Muscle Testing, CI = Confidence Interval.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of Investigational Medicinal Product (on Day 1).

Note: Missing MMT-12 Score were imputed using multiple imputation as described in Statistical Analysis Plan section 11.1.1.

Note: The change from Baseline in MMT-12 Score is analyzed using a mixed model repeated measures (MMRM) with unstructured covariance structure for Dominant Hand and unstructured covariance structure for [REDACTED] fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Table 14.2.2.1.2, Listing 16.2.6.2

Source: xxx

Program: xxxx.SAS

Date cut-off:YYYY-MM-DD

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Figure 14.2.2.2.2
Change from Baseline in Dynamometry Grip Strength Over Time - Part A + B
Full Analysis Set

Repeat Figure 14.2.1.1.2 for Dynamometry Grip Strength (Dominant Hand and [REDACTED])

Abbreviations: CI = Confidence Interval.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of Investigational Medicinal Product (on Day 1).

Note: Missing dynamometry grip strength were imputed using multiple imputation as described in Statistical Analysis Plan section 11.1.1.

Note: The change from Baseline in dynamometry grip strength is analyzed using a mixed model repeated measures (MMRM) with unstructured covariance structure for Dominant Hand and unstructured covariance structure for [REDACTED] fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Table 14.2.1.2.2, Listing 16.2.6.3

Source: xxx

Program: xxxx.SAS

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Figure 14.2.2.3.2
Change from Baseline in Dynamometry Quadriceps Strength Over Time - Part A + B
Full Analysis Set

Repeat Figure 14.2.1.1.2 for Dynamometry Quadriceps Strength (Dominant Leg and [REDACTED])

Abbreviations: CI = Confidence Interval.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of Investigational Medicinal Product (on Day 1).

Note: Missing Dynamometry Quadriceps Strength were imputed using multiple imputation as described in Statistical Analysis Plan section 11.1.1.

Note: The change from Baseline in dynamometry Quadriceps strength is analyzed using a mixed model repeated measures (MMRM) with unstructured covariance structure for Dominant Leg and unstructured covariance structure for [REDACTED] fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Table 14.2.2.3.2, Listing 16.2.6.4

Source: xxx

Program: xxxx.SAS

Date cut-off: YYYY-MM-DD

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Figure 14.2.2.4.2
Change from Baseline in mTUG Over Time - Part A + B
Full Analysis Set

Repeat Figure 14.2.1.1.2 for mTUG

Abbreviations: mTUG = Modified Timed Up and Go, CI = Confidence Interval.

Note: The baseline value is defined as the last non-missing valid value prior to first administration of Investigational Medicinal Product (on Day 1).

Note: Missing mTUG were imputed using multiple imputation as described in SAP section 11.1.1.

The change from Baseline in mTUG is analyzed using a mixed model repeated measures (MMRM) with unstructured covariance structure, fixed effects for treatment, visit and visit by treatment interaction as the fixed effects, baseline score as a covariate, and subject as the repeated random effect.

Cross Reference: Table 14.2.2.4.2, Listing 16.2.6.5

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