TRIAL STATISTICAL ANALYSIS PLAN

Document No.:	**c44820273-01**
BI Trial No.:	**1447-0007**
Title:	The effect of multiple doses of BI 1569912 on the single-dose pharmacokinetics of repaglinide, midazolam and bupropion following oral administration in healthy male and female subjects (an open-label, 2-period fixed-sequence trial) (Protocol Version 1 [c43123112-01]).
Investigational Product:	BI 1569912
Responsible trial statistician:	[redacted] Phone: [redacted] Fax:
Date of statistical analysis plan:	10 OCT 2024
Version:	1.0

1. TABLE OF CONTENTS

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2. LIST OF ABBREVIATIONS

See Medicine Glossary:

Term	Definition / description
ALT	Alanine Aminotransferase
ANOVA	Analysis of variance
AST	Aspartate Aminotransferase
$AUC_{0-\infty}$	Area under the concentration-time curve of the analyte in plasma over the time interval from 0 extrapolated to infinity
AUC_{0-tz}	Area under the concentration-time curve of the analyte in plasma over the time interval from 0 to the last quantifiable data point
BMI	Body mass index
CADSS	Assessment of dissociative symptoms
CI	Confidence interval
C_{max}	Maximum measured concentration of the analyte in plasma
CTP	Clinical trial plan
CTR	Clinical trial report
CV	Arithmetic Coefficient of Variation
DILI	Drug induced liver injury
gCV	Geometric Coefficient of Variation
gMean	Geometric Mean
Max	Maximum
Min	Minimum
N	Number non-missing observations
P10	10^{th} percentile
P90	90^{th} percentile
PKS	PK parameter analysis set
Q1	1^{st} quartile
Q3	3^{rd} quartile
q.d.	Quaque die, once daily
R	Reference treatment
RPM	Report Planning Meeting
RAGe	Report Appendix Generator system

Term	Definition / description
SD	Standard Deviation
SMWQ	Study Medication Withdrawal Questionnaire
T	Test treatment
TS	Treated Set
TSAP	Trial Statistical Analysis Plan
ULN	Upper Limit of Normal

3. INTRODUCTION

As per ICH E9 (1), the purpose of this document is to provide a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and to include detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.

This trial statistical analysis plan (TSAP) assumes familiarity with the Clinical Trial Protocol (CTP), including Protocol Amendments. In particular, the TSAP is based on the planned analysis specification as written in CTP Section 7 “Statistical Methods and Determination of Sample Size”. Therefore, TSAP readers may consult the CTP for more background information on the study, e.g., on study objectives, study design and population, treatments, definition of measurements and variables, planning of sample size, randomization.

Study data (including data entered in the RAVE EDC system and external data provided by suppliers) will be stored in a Clinical Data Repository (CDR).

Pharmacokinetic (PK) parameters will be calculated using Phoenix WinNonlin™ software (version 8.1.1 or higher, [redacted]) or SAS Version 9.4 (or later version).

The statistical analyses will be performed within the validated working environment CARE, including SAS™ (current Version 9.4, by [redacted]), and a number of SAS™-based tools (e.g., macros for the analyses of AE data or laboratory data; Report Appendix Generator system (RAGe) for compilation/formatting of the CTR appendices).

4. CHANGES IN THE PLANNED ANALYSIS OF THE STUDY

All analyses as planned in the CTP will be performed and are described in more detail in this TSAP.

5. ENDPOINTS

5.1 PRIMARY ENDPOINTS

Section 2.1.2 of the CTP:

The following pharmacokinetic parameters will be determined for repaglinide, midazolam and bupropion (specifically, S-bupropion and total bupropion) when administered without BI 1569912 and co-administered at BI 1569912 steady-state:

- *$AUC_{0-\infty}$ (area under the concentration-time curve of the analyte in plasma over the time interval from 0 extrapolated to infinity)*

5.2 SECONDARY ENDPOINTS

5.2.1 Key secondary endpoints

This section is not applicable as no key secondary endpoints have been defined in the CTP.

5.2.2 Secondary endpoints

Section 2.1.3 of the CTP:

The following pharmacokinetic parameters will be determined for repaglinide, midazolam and bupropion (specifically, S-bupropion and total bupropion) when administered without BI 1569912 and co-administered at BI 1569912 steady-state:

- *AUC_{0-tz} (area under the concentration-time curve of the analyte in plasma over the time interval from 0 to the last quantifiable data point)*
- *C_{max} (maximum measured concentration of the analyte in plasma)*

[redacted]

Safety and tolerability endpoints

Section 2.2.2.2 of the CTP:

Safety and tolerability of BI 1569912 will be assessed based on:

- *Adverse events (including clinically relevant findings from the physical examination)*
- *Suicidality assessment (C-SSRS)*
- *Safety laboratory tests*
- *12-lead ECG*
- *Vital signs (blood pressure, pulse rate)*
- *Standardized mental and neurological assessment*

[redacted]

6 GENERAL ANALYSIS DEFINITIONS

6.1 TREATMENTS

For basic study information on treatments to be administered and selection of doses, refer to CTP Sections 3 and 4.

This trial is designed as non-randomised, open-label, two-period fixed-sequence trial in healthy male and female subjects. No wash-out phase between the two periods is mandatory. However, e. g. for logistical reasons, period 1 and 2 may be separated by up to 14 days.

For details of dosage and formulation see Table 6.1:1 below.

Table 6.1: 1 Treatments and labels used in the analysis

Treatment		Short label
R1	repaglinide, tablet, 0.5 mg, p.o., single dose	REPA
R2	midazolam, solution for injection (used as oral solution) 5 mg/5 ml, 2 mg, p.o., single dose	MID
R3	bupropion, extended-release tablet, 150 mg, p.o., single dose	BUP
	BI 1569912, [redacted]	BI
T1	BI 1569912, [redacted] + repaglinide, tablet, 0.5 mg, p.o., single dose	BI + REPA
T2	BI 1569912, [redacted] + midazolam, solution for injection (used as oral solution) 5 mg/5 ml, 2 mg, p.o., single dose	BI + MID
T3	BI 1569912, [redacted] + bupropion, extended-release tablet, 150 mg, p.o., single dose	BI + BUP

R denotes reference treatment (R1, R2, R3) and T test treatment (T1, T2, T3).

Section 1.2.5 of the CTP:

[redacted]

[redacted]

Based on this, the following study phases will be defined for the analysis of adverse events (AEs):

Screening and on-treatment phases

[redacted]

Follow-up phases

Not all follow-up phases are applicable if trial drugs will be administered as scheduled according to the CTP flow chart (p. 4-10 of the CTP). The follow-up phases which are highlighted grey will not be applicable if there are no deviations from the CTP flow chart.

Section 7.2.5 of the CTP:
Note that AEs occurring after the last per protocol contact but entered before database lock will be reported to Pharmacovigilance only and will not be captured in the trial database.

The following AE displays will be provided in the report:

In Section 9.3 and Appendix 10.5.1.8 (for ClinicalTrials.gov and EudraCT only) of the CTR displays, the on treatment phase will be analysed (labelled with the short label of the study treatment). The screening and follow-up phases will not be included in this analysis.

The following totals will be provided in addition for Section 9.3:

- a total over all on treatment phases **("Total")**
- a total over all treatment phases involving BI **("BI Total")**

In Section 9.4 and Appendix 10.6 (Listings) of the CTR displays, the screening period, as well as the follow-up phases will additionally be included.

For detailed information on the handling of the treatments refer to Technical TSAP ADS (analysis data set) plan and Analysis Data Reviewers guide.

6.2 IMPORTANT PROTOCOL DEVIATIONS

Data discrepancies and deviations from the CTP will be identified for all treated subjects. Consistency check listings (for identification of deviations of time windows) and a list of protocol deviations (e.g. deviations in drug administration, in blood sampling times, etc.) will be provided to be discussed at the Report Planning Meeting (RPM). At this meeting, all manual deviations identified at the sites by the CRAs and deviations too complex to program will be reviewed by the trial team to decide which are considered important. For definition of important protocol deviations (iPD), and for the process of identification of these, refer to the Boehringer Ingelheim (BI) SOP "Identify and Manage Important Protocol Deviations (iPD)" (2).

Important protocol deviation categories are pre-specified in the iPD specification file (DV domain) (3). IPDs will be identified no later than in the Report Planning Meeting, and the iPD categories will be updated as needed.

If any iPDs are identified, they are to be summarised into categories and will be captured in the iPD specification file (DV domain) (3) and in the decision log (4). Both documents will be stored within the TMF in EDMS.

The iPDs will be summarized and listed in the CTR.

6.3 INTERCURRENT EVENTS

This section is not applicable.

6.4 SUBJECT SETS ANALYSED

Section 7.2.1.1 of the CTP:

Statistical analyses will be based on the following analysis sets:

- *Treated set (TS): The treated set includes all subjects who were treated with at least one dose of trial drug. The treated set will be used for safety analyses.*
- *Pharmacokinetic parameter analysis set (PKS): This set includes all subjects in the treated set (TS) who provide at least one PK endpoint that was defined as primary or secondary and was not excluded due to a protocol deviation relevant to the evaluation of PK or due to PK non-evaluability (as specified in the following* CTP *subsection 'Pharmacokinetics'). Thus, a subject will be included in the PKS, even if he/she contributes only one PK parameter value for one period to the statistical assessment.*

[...]

For details about the evaluation of pharmacokinetic parameters such as criteria for inclusion and exclusion of data points into the evaluation of pharmacokinetic parameters see CTP, 7.2.1.2.

Table 6.4: 1 Subject sets analysed

	Subject set	
Class of analysis	TS	PKS
Primary/secondary and further PK endpoints		X
Safety & treatment exposure & iPD	X	
Disposition, demographics & baseline conditions	X	

[redacted]

6.6 HANDLING OF MISSING DATA AND OUTLIERS

Handling of missing data and outliers will be performed as described in the CTP, Section 7.3:

Section 7.3.1 of the CTP: *It is not planned to impute missing values for safety parameters.*

Missing or incomplete AE dates are imputed according to BI standards (see "Handling of Missing and Incomplete AE Dates") (5).

Missing data and outliers of PK data are handled according to BI standards (see "Standards and processes for analyses performed within Clinical Pharmacokinetics/Pharmacodynamics" (6) and "Noncompartmental Pharmacokinetic / Pharmacodynamic Analyses of Clinical Studies" (7)).

PK parameters that cannot be reasonably calculated based on the available drug concentration-time data will not be imputed.

6.7 BASELINE, TIME WINDOWS AND CALCULATED VISITS

The baseline value for vital signs and laboratory analysis is defined as the last measurement before first trial drug administration in each treatment period. The safety laboratory measurement at ptm 168:00 will be considered off-treatment and used as baseline value for safety laboratory values in period 2.

For acceptable deviations from the scheduled time of measurements as well as the order of measurements that are scheduled for the same time according to CTP Flow Chart, see Section 6.1 of the CTP.

Adherence to time windows will be checked via the consistency check listings at the RPM.

Unscheduled measurements of laboratory data and vital signs data will be assumed to be repeat measurements of the most recent scheduled measurement (e.g. for follow-up or confirmation of a particular value). Therefore, unscheduled measurements will be assigned to the planned time point of the previous scheduled measurement.

7 PLANNED ANALYSIS

Safety analysis (refer to Section 7.8) will be performed by [redacted] and will be presented in Sections 9.1 to 9.4 of the CTR and in Appendix 10.6 and 10.5.1.

Inferential statistical analyses of PK endpoints (refer to Section 7.4) will also be performed by [redacted] and will be presented in Section 15.5 of the CTR and in Appendix 10.5.3.

Descriptive data analysis of PK endpoints and concentrations will be performed by the [redacted] and will be presented in Section 9.6 of the CTR and in Appendix 10.5.5.

The format of the listings and tables will follow the BI standards (see "Standards for Reporting of Clinical Trials and Project Summaries" (8)) with the exception of those generated for PK-calculations following BI standards for PK/PD analysis (9).

The individual values of all subjects will be listed, sorted by subject number and visit. The listings will be included in Appendix 10.6 of the CTR.

The following standard descriptive statistical parameters will be displayed in summary tables of continuous variables:

N	number non-missing observations
Mean	arithmetic mean
SD	standard deviation
Min	minimum
Median	median
Max	maximum

For analyte concentrations and PK parameters, the following descriptive statistics will additionally be calculated:

Nobs	number of observations
CV	arithmetic coefficient of variation
gMean	geometric mean
gCV	geometric coefficient of variation

For PK parameters, the following descriptive statistics will additionally be calculated:

P10	10^{th} percentile
Q1	1^{st} quartile
Q3	3^{rd} quartile
P90	90^{th} percentile

The data format for descriptive statistics of concentrations will be identical to the data format of the respective concentrations. The descriptive statistics of PK parameters will be calculated using the individual values with the number of decimal places as provided by the evaluation

program. Then the individual values as well as the descriptive statistics will be reported with three significant digits in the CTR.

The gMeans and gMean ratio based on the inferential statistics will be reported with maximum of 2 decimal places.

Tabulations of frequencies for categorical data will include all possible categories available in the CRF and will display the number of observations in a category, as well as the percentage (%). The precision for percentages should be one decimal point, unless the denominator is smaller than 100 (in all treatment columns), in which case percentages are given in integer numbers. The category 'missing' will be displayed only if there are actually missing values.

Units of variables should be given in the titles or column/row descriptors in brackets (e.g. (mg)).

Exclusion of PK parameters

The ADS “ADPP” (PK parameters) contains column variables APEX and APEXCO indicating inclusion/exclusion (APEX) of a PK parameter and an analysis flag comment (APEXCO). All analyses based on the PKS will include parameters only if they are not flagged for exclusion, that is APEX is equal to “Included”.

Exclusion of PK concentrations

The ADS “ADPC” (PK concentrations per time-point or per time-interval) contains column variables ACEX and ACEXCO indicating inclusion/exclusion (ACEX) of a concentration and an analysis flag comment (ACEXCO). Exclusion of a concentration depends on the analysis flag comment ACEXCO. For example, if ACEXCO is set to

- ‘ALL CALC’, the value will be excluded for all types of analyses based on concentrations.
- ‘DESC STATS’ the value will be excluded from descriptive evaluations per planned time point/time interval.
- ‘HALF LIFE’, the value will be excluded from half-life calculation (and, as a consequence, any calculation that relies on λ_z) only; the value is included for all other analyses.

If ACEXCO contains the addition ‘TIME VIOLATION’ or ‘TIME DEVIATION’ the value can be used for further analyses based on actual times. Excluded concentration itself will be listed in the CTR associated with an appropriate flag.

Further details are given in “Noncompartmental Pharmacokinetic / Pharmacodynamic Analyses of Clinical Studies” (7) and “Description of Analytical Transfer Files and PK/PD Data Files” (10).

7.1 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Only descriptive statistics are planned for this section of the report, based on the TS. A total column will be displayed only.

7.2 CONCOMITANT DISEASES AND MEDICATION

Only descriptive statistics are planned for this section of the report, based on the TS.

Concomitant diseases and non-drug therapies will be coded according to the version defined in the decision log (4) of the coding system of the Medical Dictionary for Drug Regulatory Activities (MedDRA). Concomitant medications will be coded according to the most recent version of the World Health Organization Drug Dictionary (WHO-DD). The coding version number will be displayed as a footnote in the respective output.

Section 7.2.5 of the CTP:
Previous and concomitant therapies will be presented per treatment sequence without consideration of time intervals and treatment periods.

The diagnoses, non-drug therapies and medications will be listed. Subjects without any concomitant diagnoses or concomitant therapies will be marked with a “No” in the respective column.

The relevance of the concomitant therapies to the evaluation of PK data will be decided no later than at the RPM.

7.3 TREATMENT COMPLIANCE

Section 4.3 of the CTP:
Compliance will be assured by administration of all trial medication in the trial centre under supervision of the investigating physician or a designee. The measured plasma concentrations of trial medication will provide additional confirmation of compliance.

It is not intended to list the compliance separately. Any deviations from complete drug intake will be addressed in the RPM and described in the CTR.

7.4 PRIMARY OBJECTIVE ANALYSIS

7.4.1 Main analysis

Independent of the main objectives stated in the CTP, this section describes further details of the primary endpoint analyses outlined in the CTP.

Section 7.2.2 of the CTP:
The statistical model used for the analysis of the primary endpoints will be an analysis of variance (ANOVA) model on the logarithmic scale. That is, the PK endpoints will be log-transformed (natural logarithm) prior to fitting the ANOVA model. This model will include effects accounting for the following sources of variation: subject and treatment. The effect 'subject' will be considered as random, whereas the effect 'treatment' will be considered as fixed. The model is described by the following equation:

$y_{km} = \mu + s_m + \tau_k + e_{km}$, *where*

y_{km} = *logarithm of response measured on subject m receiving treatment k,*

μ = *the overall mean,*

s_m = *the effect associated with the* m^{th} *subject, m = 1, 2, ..., n*

τ_k = *the* k^{th} *treatment effect, k = 1, 2,*

e_{km} = *the random error associated with the* m^{th} *subject who received treatment k.*

where $s_m \sim N(0, \sigma_B^2)$ *i.i.d.,* $e_{km} \sim N(0, \sigma_W^2)$ *i.i.d. and* s_m, e_{km} *are independent random variables.*

Point estimates for the ratios of the geometric means (test/reference for each pairwise comparison) for the primary endpoints (see CTP *Section 2.1) and their two-sided 90% confidence intervals (CIs) will be provided.*

For the primary endpoint, the difference between the expected mean for log response of the test treatment – log response of the reference treatment will be estimated by the difference in the corresponding adjusted means (Least Squares Means). Additionally, their two-sided 90% confidence intervals will be calculated based on the residual error from the ANOVA and quantiles from the t-distribution. These quantities will then be back-transformed to the original scale to provide the point estimate and 90% CIs for each endpoint. […]

The implementation for this analysis will be accomplished by using the CSD macros based on the PKS. The following SAS code can be used:

```
PROC MIXED DATA=indata METHOD=REML;
   CLASS subject treatment;
   MODEL logpk = treatment / DDFM=KR;
   RANDOM subject;
   LSMEANS treatment / PDIFF CL ALPHA=0.1;
   ESTIMATE 'T-R' treatment 1 -1;
```

RUN;

7.5 SECONDARY OBJECTIVE ANALYSIS

Independent of the main objectives stated in the CTP, this section describes further details of the secondary endpoint analyses.

7.5.1 Key secondary objective analysis

This section is not applicable as no key secondary endpoint has been specified in the protocol.

7.5.2 Secondary objective analysis

Section 7.2.3 of the CTP:

The secondary endpoints (refer to CTP Section 2.1.3) will be calculated according to the relevant BI internal procedures and will be assessed statistically using the same methods as described for the primary endpoints.

7.7 EXTENT OF EXPOSURE

Descriptive statistics are planned for this section of the report based on the TS. The date and time of drug administration will be listed for each subject.

7.8 SAFETY ANALYSIS

All safety analyses will be performed on the TS.

The safety data for treated subjects who failed to complete the study (dropouts or withdrawals) will be reported as far as their data are available. All withdrawals will be documented and the reason for withdrawal recorded.

7.8.1 Adverse Events

AEs will be coded using MedDRA. The coding version number will be displayed as a footnote in the respective output.

Unless otherwise specified, the analyses of AEs will be descriptive in nature. All analyses of AEs will be based on the number of subjects with AEs and NOT on the number of AEs. BI standards as presented in "Analysis and Presentation of Adverse Event Data from Clinical Trials – Display Template" (11) and "Analysis and Presentation of AE data from clinical trials" (12) will be applied.

The analysis of AEs will be based on the concept of treatment emergent AEs. That means that all AEs will be assigned to 'screening', 'on-treatment' or 'follow-up' phases as defined in Section 6.1. AEs will be analysed based on actual treatments, as defined in Table 6.1: 1.

According to the clinical study protocol, adverse events of special interest (AESI) will be analysed:

Section 5.2.6.1.4 of the CTP:

The following are considered as AESIs:

- *Potential severe DILI*

A potential severe Drug Induced Liver Injury (DILI) that requires follow-up is defined by the following alterations of hepatic laboratory parameters:

- *An elevation of AST (aspartate aminotransferase) and/or ALT (alanine aminotransferase) ≥3-fold ULN combined with an elevation of total bilirubin ≥2-fold ULN measured in the same blood sample, or in samples drawn within 30 days of each other, or*

- *Aminotransferase (ALT, and/or AST) elevations ≥5-fold ULN*

These lab findings constitute a hepatic injury alert and the subjects showing these lab abnormalities need to be followed up according to the 'DILI checklist' provided in the ISF. In case of clinical symptoms of hepatic injury (icterus, unexplained encephalopathy, unexplained coagulopathy, right upper quadrant abdominal pain, etc.) without lab results (ALT, AST, total bilirubin) available, the Investigator should make sure that these parameters are analysed, if necessary in an unscheduled blood test. Should the results meet the criteria of hepatic injury alert, the procedures described in the DILI checklist should be followed.

According to ICH E3 (13), in addition to Deaths and serious adverse events, 'other significant' AEs need to be listed in the clinical trial report. These will be any non-serious adverse event that led to an action taken with study drug (e.g. discontinuation or dose reduced or interrupted).

An overall summary of adverse events will be presented.

The frequency of subjects with AEs will be summarised by treatment, primary system organ class (SOC) and preferred term (PT). Separate tables will be provided for subjects with serious AEs, for subjects with investigator-defined drug-related AEs, for subjects with investigator-defined drug-related serious adverse events, for subjects with AESIs and for subjects with AEs leading to discontinuation. In addition, the frequency of subjects with AEs will be summarised by worst intensity, treatment, primary system organ class (SOC) and preferred term (PT).

The system organ classes will be sorted by default alphabetically, PTs will be sorted by descending frequency (within SOC).

In addition, for disclosure of AEs in EudraCT and ClinicalTrials.gov frequencies of subjects with non-serious AEs that had an incidence of > 5% for at least one treatment will be summarised by treatment, primary SOC and PT. The frequency of subjects with SAEs will also be summarised.

7.8.2 Laboratory data

The analyses of laboratory data will be descriptive in nature and will be based on BI standards outlined in “Handling, Display and Analysis of Laboratory Data” (14). Analyses will be based on normalised values, which means transforming to a standard unit and a standard reference range. The original values will be analysed if the transformation into standard unit is not possible for a parameter.

Laboratory data will be analysed qualitatively via comparison of laboratory data to their reference ranges. Values outside the reference range as well as values defined as possibly clinically significant will be flagged in the data listings.

Clinically relevant findings in laboratory data will be reported as baseline conditions (at screening) or as AEs (during the trial) if judged clinically relevant by the investigator, and will be analysed as such (checked at the RPM at the latest).

For post-dose measurements, descriptive statistics including change from baseline will be calculated by planned time point based on the first value of the subject at that planned time point (or assigned to that planned time point). The baseline value is defined as the last measurement before first drug administration in each period.

7.8.3 Vital signs

Descriptive statistics over time including change from baseline will be performed for vital signs (blood pressure and pulse rate). In the listing, the change from baseline will also be displayed.

For post-dose measurements of vital signs, descriptive statistics will be calculated by planned time point based on the first value of the subject at that planned time point (or assigned to that

planned time point). For baseline value, the last measurement before first drug administration in each treatment period will be used.

Clinically relevant findings will be reported as baseline conditions (at screening) or as AEs (during the trial) if judged clinically relevant by the investigator, and will be analysed as such.

7.8.4 ECG

Clinically relevant abnormal findings will be reported as adverse events.
No separate listing or analysis of continuous ECG monitoring will be prepared.

7.9 OTHER ANALYSIS

Physical examination

Physical examination findings will be reported as relevant medical history/baseline condition (i.e., a condition already existent before intake of trial drug) or as AEs and will be summarised as such.

No separate listing or analysis of physical examination findings will be prepared.

Assessment of suicide ideation:

Suicidality questioning will be assessed by the C-SSRS questionnaire (CTP Section 5.2.5.1). Results regarding the C-SSRS will only be listed.

Mental and neurological assessment:

For the standardized mental and neurological assessment see CTP Section 5.2.5.2. Mental and neurological assessment findings will be reported as baseline conditions or adverse events, respectively.

7.9.1 Biomarker analyses

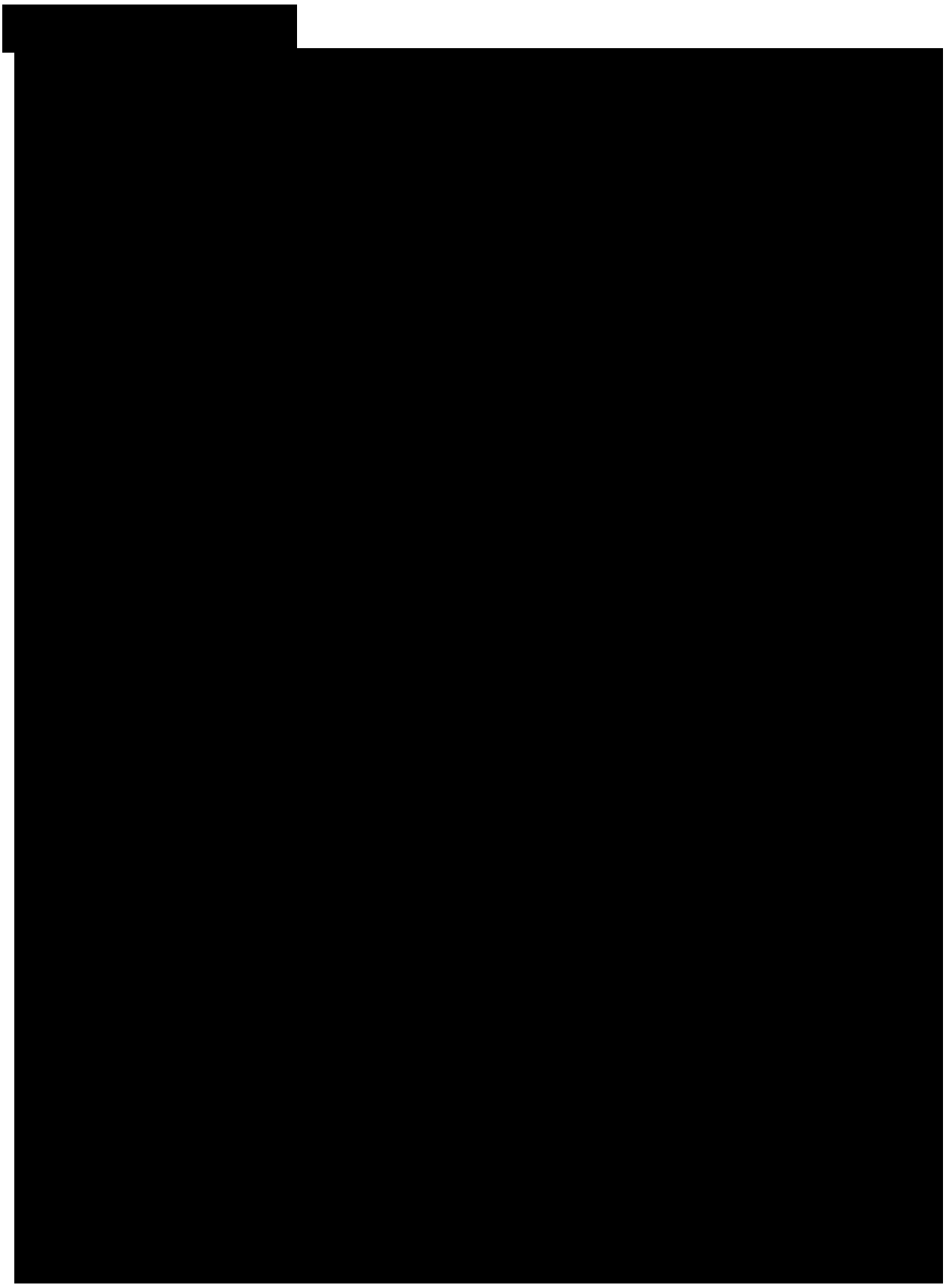
No biomarker analysis is planned.

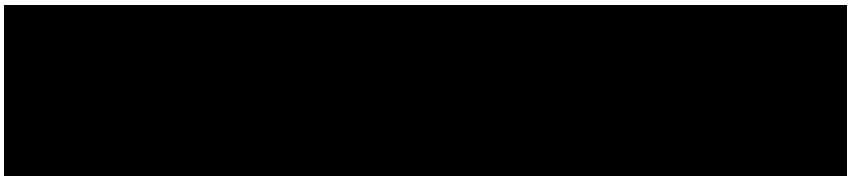
7.9.2 PK / PD analyses

No PK/PD analysis is planned.

8 TIMEPOINT OF RELEASE OF TREATMENT INFORMATION

Not applicable due to open-label fashion of the trial as described in the CTP section 4.1.5. The treatment information will be loaded into the trial database at trial initiation.





11 HISTORY TABLE

Table 11: 1 History table

Version	Date (DD-MMM-YY)	Author	Sections changed	Brief description of change
1.0	**10-OCT-24**	[redacted]	None	This is the final TSAP.