TRIAL STATISTICAL ANALYSIS PLAN

c31606953-01

BI Trial No.:	1371-0022
Title:	Formulation selection and subsequent optimization of two different oral formulations of BI 894416 in healthy male subjects (open-label, randomised, single-dose study in two parts; trial part 1: five-period crossover design with an additional sixth period in a fixed sequence; trial part 2: three-period crossover followed by a two-period crossover design) Final protocol (including protocol revision 1 (c28590127-04))
Investigational Product:	BI 894416
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Date of statistical analysis plan:	05 FEB 2021 SIGNED
Version:	1

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2. LIST OF ABBREVIATIONS

Term	Definition / description
ALT	Alanine aminotransferase
ANOVA	Analysis of variance
AST	Aspartate aminotransferase
AUC_{0-tz}	Area under the concentration-time curve of the analyte in plasma over the time interval from 0 the last quantifiable time point
$AUC_{0-\infty}$	Area under the concentration-time curve of the analyte in plasma over the time interval from 0 extrapolated to infinity
BI	Boehringer Ingelheim
BP	Blood pressure
CV	Arithmetic coefficient of variation
ER	Extended release
FRR	Fast release rate
gCV	Geometric coefficient of variation
gMean	Geometric mean
IQRMP	Integrated quality and risk management plan
IR	Immediate release
MedDRA	Medical Dictionary for Regulatory Activities
PKS	Pharmacokinetic parameter set
PR	Pulse rate
RAGe	Report appendix generator
SD	Standard Deviation
SOC	System Organ Class
SRR	Slow release rate
TS	Treated set
ULN	Upper limit of normal range

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 revised CTP, and to include detailed procedures for executing the statistical analysis of the primary variables and other data.

This TSAP assumes familiarity with the CTP and its 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, randomisation.

Study data as collected in the eCRF will be stored in a trial database within the RAVE EDC system. All study data also including external data will then be uploaded to the CDR data warehouse.

The statistical analyses will be performed within the validated working environment CARE, including SAS™ (current Version 9.4, by SAS Institute Inc., Cary, NC, USA), 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).

PK parameters will be calculated using Phoenix WinNonlin™ software (version Phoenix 6.3, Certara USA Inc., Princeton, NJ, USA).

4. CHANGES IN THE PLANNED ANALYSIS OF THE STUDY

The trial part 1 was performed according to the CTP and the trial was terminated before any subject in trial part 2 was treated. Therefore, the analysis described in this TSAP refers to trial part 1 only.

All analyses described in this TSAP are in accordance with the statistical methods described in the revised CTP.

5. ENDPOINTS

5.1 PRIMARY ENDPOINT

The primary endpoint is a PK endpoint of BI 894416, as defined in **Section 2.1.2 of the CTP**:

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

5.2 SECONDARY ENDPOINT

5.2.1 Key secondary endpoint

Not applicable

5.2.2 Secondary endpoint

The secondary endpoint is a PK endpoint of BI 894416, as defined in **Section 2.1.2 of the CTP**:

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

5.3 FURTHER ENDPOINTS

[redacted]

5.3.2 Safety parameters

Safety and tolerability of BI 894416 will be assessed based on further safety endpoint defined in **Section 2.2.2.2 of the CTP**:

- *Adverse events (including clinically relevant findings from the physical examination)*
- *Safety laboratory tests*
- *12-lead ECG*
- *Vital signs (blood pressure, pulse rate)*

5.4 OTHER VARIABLES

5.4.1 Demographic and other baseline characteristics

CTP Section 5.2.1: *At screening, the medical examination will include demographics, height and body weight, smoking and alcohol history (alcohol history results are not mandatory to be entered into CRF or to be reported), relevant medical history and concomitant therapy, review of inclusion and exclusion criteria, review of vital signs (BP, PR), 12-lead ECG, laboratory tests, and a physical examination.*

Age (years) will be determined as the difference between year of birth and year of informed consent.

Body mass index will be calculated as weight (kg) / (height (m))^2.

5.4.2 Treatment compliance and treatment exposure

Treatment compliance will not be analysed as a specific endpoint, cf. Section 4.3 of the CTP.

Since only single doses will be applied per treatment period, the date and time of drug administration along with measured drug plasma concentrations will ensure treatment exposure.

[redacted]

6. GENERAL ANALYSIS DEFINITIONS

6.1 TREATMENTS

For basic study information on treatments to be administered, assignment of treatment groups, and selection of doses, cf. Section 4 of the CTP.

The trial is divided into two parts but only trial part 1 was performed.

In **trial part 1**, each subject is planned to be treated in five subsequent treatment periods (five-period cross-over) with one single dose in each treatment period followed by one single dose in a sixth treatment period in a fixed sequence.

Treatments in the five-period cross-over:

- Reference treatment 1 (R1) – 60mg tab IR fasted:
  60 mg of BI 894416, IR tablets under fasted conditions

- Test treatment 1 (T1) – 62.5mg tab FRR fasted:
  62.5 mg of BI 894416, ER tablet (fast release rate) under fasted conditions

- Test treatment 2 (T2) – 62.5mg tab SRR fasted:
  62.5 mg of BI 894416, ER tablet (slow release rate) under fasted conditions

- Test treatment 3 (T3) – 62.5mg cap FRR fasted:
  62.5 mg of BI 894416, ER capsule (fast release rate) under fasted conditions

- Test treatment 4 (T4) – 62.5mg cap SRR fasted:
  62.5 mg of BI 894416, ER capsule (slow release rate) under fasted conditions

Each subject is planned to be randomly allocated to one of five treatment sequences (T3-R1-T1-T4-T2, T2-T1-T3-R1-T4, T4-T3-R1-T2-T1, T1-T4-T2-T3-R1 and R1-T2-T4-T1-T3, cf. Table 6.1: 2).

Treatments in the fixed sequence:

- Test treatment 5 (T5) – 62.5mg tab SRR fed:
  62.5 mg of BI 894416 ER, tablet (slow release rate) after a high fat breakfast

- Test treatment 6 (T6) – 62.5mg cap SRR fed:
  62.5 mg BI 894416, capsule (slow release rate) after a high fat breakfast

Subject will be randomly allocated to either T5 or T6, stratified by sequence (cf. Table 6.1: 2 for an overview of the treatment sequences).

For statistical analysis of AEs, safety laboratory data and vital signs, the following analysis phases are defined for each subject:

Table 6.1: 1 Flow chart of analysis phases for statistical analyses of AEs

Study analysis phase	Label	Start (inclusive)	End (exclusive)
Screening	**Screening**	Date of informed consent	Date/time of administration of BI 894416 in any formulation
On-treatment	**BI 894416** respectively	Date/time of administration of BI 894416 in any formulation	Date/time of administration of BI 894416 in another formulation or 12:00 a.m. on day after subject's trial termination date, whichever occurs earlier

Analysis phases for statistical analysis of AEs are defined for each subject as described in the table above.

CTR Section 15, Appendix 16.1.13.1.8.2 and Appendix 16.1.13.1.8.3 AE displays will present results for the on-treatment phase only.

In disposition, demographics and baseline characteristics, all subjects will be analysed together (i.e., one “BI 894416” column). Exposure will be summarised by period and treatment formulation.

The statistical analyses of safety laboratory tests and vital signs will be performed including all subject together (i.e., one “BI 894416” column), with clear differentiation between baseline (cf. Section 6.7) and on-treatment measurements.

Table 6.1: 2 Overview of treatment sequences

Trial part 1
T3-R1-T1-T4-T2-T5
T3-R1-T1-T4-T2-T6
T2-T1-T3-R1-T4-T5
T2-T1-T3-R1-T4-T6
T4-T3-R1-T2-T1-T5
T4-T3-R1-T2-T1-T6
T1-T4-T2-T3-R1-T5
T1-T4-T2-T3-R1-T6
R1-T2-T4-T1-T3-T5
R1-T2-T4-T1-T3-T6

More details on the technical implementation of these analyses are provided in the ADS Plan of this TSAP.

6.2 IMPORTANT PROTOCOL DEVIATIONS

Consistency check listings (for identification of deviations from 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, it will be decided whether a discrepant data value can be used in the analyses or whether it must be corrected in the clinical database. Each protocol deviation must be assessed to determine whether it is an important protocol deviation (iPD). For definition of iPDs, and for the process of identification of these, refer to the BI reference document “Identify and Manage Important Protocol Deviations (iPD)” (2).

If any iPDs are identified, they are to be summarised into categories and will be captured in the decision log. Categories which are considered to be iPDs in this trial are defined in the integrated quality and risk management plan (IQRMP). If the data show other iPDs, the definition in the IQRMP and the table below will be supplemented accordingly by the time of the RPM. Additionally, all iPDs will be documented in the DV sheet.

iPDs will be summarized and listed. Table 6.2: 1 specifies which kind of iPDs could potentially lead to exclusion from which analysis set (cf. Section 6.3). The decision on exclusion of subjects from analysis sets will be made at the latest at the RPM, after discussion of exceptional cases and implications for analyses.

Table 6.2: 1 Handling of iPDs

iPD code	iPD Category & Brief Description	Excluded from which analysis set
A1	Inclusion criteria not met	PKS
A2	Exclusion criteria violated	PKS
B1	Informed consent not available/not done	TS, PKS
B2	Informed consent too late	None
C1	Incorrect trial medication taken	PKS
C2	Randomisation not followed	PKS
C3	Non-compliance	PKS
C4	Medication code broken inappropriately	PKS
C5	Incorrect intake of trial medication	PKS
C6	Improper washout between treatments	PKS
D1	Prohibited medication use	PKS
D2	Mandatory medication not taken	PKS
D3	Improper washout of concomitant medication	PKS
E1	Certain violations of procedures used to measure primary or secondary data	PKS
F1	Certain violations of time schedule used to measure primary or secondary data	PKS
G1	Incorrect intake of meal	PKS
H1	PDs affecting efficacy, safety and rights	TS, PKS

6.3 SUBJECT SETS ANALYSED

Subject sets will be used as defined in the CTP, Section 7.3.

Table 6.3: 1 Subject sets analyzed

	Subject set	
Class of endpoint	TS	PKS
Disposition	X	
iPDs	X	
Primary PK endpoint		X
Secondary PK endpoint		X
[redacted]		
Safety parameters & treatment exposure	X	
Demographic/baseline endpoints	X	

6.4 SUBGROUPS

A subgroup analysis is not planned.

6.5 POOLING OF CENTRES

This section is not applicable, because the study was performed in only one centre.

6.6 HANDLING OF MISSING DATA AND OUTLIERS

Data of screened subjects who were withdrawn from the trial prior to first administration of any study drug will not be reported in the CTR.

Data of subjects who failed to complete all periods of the study (dropouts or withdrawals) will be reported in the CTR as far as their data are available. All withdrawals will be documented and the reason for withdrawal reported in the CTR.

CTP Section 7.5.1: *It is not planned to impute missing values for safety parameters.*

One exception where imputation might be necessary for safety evaluation are AE dates. Missing or incomplete AE dates are imputed according to BI standards (3).

Missing data and outliers of PK data are handled according to BI standards (4) and (5). **CTP Section 7.5.2**: *Pharmacokinetic 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

Baseline is defined as the last available value before any administration of BI 894416 (in any formulation).

Time windows are defined in Section 6.1 of the CTP. Adherence to time windows will be checked at the RPM.

7. PLANNED ANALYSIS

The format of the listings and tables will follow the BI guideline "Standards for Reporting of clinical trials and project summaries" (6).

The individual values of all subjects will be listed. Listings will be sorted by treatment sequence, subject number and visit (if visit is applicable in the respective listing). AE listings will be sorted by assigned treatment (see Section 7.8.1 below for details). The listings will be contained in Appendix 16.2 (SDL) of the CTR.

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

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

For plasma concentrations as well as for all PK parameters the following descriptive statistics will additionally be calculated:

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 plasma concentrations will be identical with 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.

Tabulations of frequencies for categorical data will include all possible categories and will display the number of observations in a category as well as the percentage (%) relative to the respective treatment group. Percentages will be rounded to one decimal place. The category missing will be displayed if and only if there actually are missing values. Percentages will be based on all subjects in the respective subject set whether they have non-missing values or not.

7.1 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Only descriptive statistics are planned for this section of the CTR.

7.2 CONCOMITANT DISEASES AND MEDICATION

Concomitant diseases will be coded according to the most recent version of MedDRA. Concomitant medication will be coded according to the most recent version of the World Health Organisation – Drug Dictionary. Concomitant non-drug therapies will be coded according to the most recent version of MedDRA.

A medication will be considered concomitant, if it

- is ongoing at the time of first study drug administration, or
- starts within the analysis phase of the respective treatment (see Section 6.1 for a definition of treatments and analysis phases).

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

Only descriptive statistics are planned for this section of the CTR.

7.3 TREATMENT COMPLIANCE

Treatment compliance will not be analyzed as a specific endpoint. Any deviations from complete intake will be addressed in the Report Planning Meeting (cf. Section 6.2) and described in the CTR.

7.4 PRIMARY ENDPOINT

7.4.1 Primary analysis of the primary endpoint

Primary analysis of the primary endpoint will be performed as defined in Section 7.3.1 of the CTP. The analysis will be based on the PKS.

To assess the relative bioavailability of extended release formulation compared with immediate release formulation on the PK of the treatment, the statistical model for the primary analysis defined in the CTP is an analysis of variance (ANOVA) model on the logarithmic scale including “sequence”, “period” and “treatment” (formulation) as fixed effect and “subject nested within sequence” as random effect. All formulation data are included in the model for each pairwise comparison. The formulations T1 (62.5mg tab FRR fasted), T2 (62.5mg tab SRR fasted), T3 (62.5mg cap FRR fasted), and T4 (62.5mg cap SRR fasted) will be compared versus R1 (60mg tab IR fasted).

To assess the relative bioavailability of BI fed compared with BI fasted, the statistical model for the primary analysis defined in the CTP is an ANOVA model on the logarithmic scale including “treatment” as fixed effect and “subject” as random effect. The model will be analysed as a two period fixed sequence cross-over model. The formulations T5 (62.5mg tab SRR fed) will be compared versus T2 (62.5mg tab SRR fasted) and T6 (62.5mg cap SRR fed) versus T4 (62.5mg cap SRR fasted).

The relative bioavailability will be estimated by the ratios of the geometric means of (test/reference) of the primary endpoint.

Exclusion of plasma concentrations

The ADS ADPC (PK concentrations per time-point or per time-interval) contains column variables ACEXC or ACEXCO indicating inclusion/exclusion (ACEXC) 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. If ACEXCO is set to "DESC STATS" the value will be excluded from descriptive evaluations per planned time point/time interval. If ACEXCO contains the addition "TIME VIOLATION" or "TIME DEVIATION", the value can be used for further analyses based on actual times. If ACEXCO is set to "HALF LIFE", the value will be excluded from half-life calculation only; the value is included for all other analyses. Excluded concentration itself will be listed in the CTR associated with an appropriate flag.

Exclusion of PK parameters

The ADS ADPP contains column variables APEXC and APEXCO indicating inclusion/exclusion (APEXC) of a PK parameter and an analysis flag comment (APEXCO). All analyses based on the PKS are based on PK parameter values which are not flagged for exclusion, i.e. with APEXC equal to "Included".

Further details are given in "Noncompartmental Pharmacokinetic / Pharmacodynamic Analyses of Clinical Studies" (4) and "Description of Analytical Transfer Files and PK/PD Data Files" (5).

7.4.2 Sensitivity analysis, subgroup analysis, exploratory analysis of the primary endpoint

The same statistical model as used for the primary analysis for the comparison of formulations (Section 7.3.1 of the CTP) will be repeated for the primary endpoint but with all sources of variation ("sequence", "subject within sequence", "period" and "treatment" (formulation)) considered as fixed effects.

Similarly, the model used for the primary analysis for the comparison of BI fed versus BI fasted will be repeated for the primary endpoint with "subject" and "treatment" as fixed effect.

Furthermore, the primary PK endpoints will be assessed descriptively. The analysis of standard PK parameters is performed according to BI standards (4).

7.5 SECONDARY ENDPOINT

7.5.1 Key secondary endpoint

Not applicable.

7.5.2 Secondary endpoint

The analysis of secondary endpoints will be based on the PKS.

The secondary endpoint will be statistically analysed in the same way as for the primary endpoint. The endpoint will also be assessed descriptively. The analysis of standard PK parameters is performed according to BI standards (4).

See Section 7.4 of this TSAP for details regarding exclusion of PK parameters and plasma concentrations.

[redacted]

7.6.2 Safety parameters

Safety endpoints and tolerability will be analysed as described in Section 7.8 of this TSAP.

7.7 EXTENT OF EXPOSURE

Descriptive statistics are planned for this section of the report.

7.8 SAFETY ANALYSIS

All safety analyses will be performed on the TS.

7.8.1 Adverse Events

AEs will be coded with the most recent version of MedDRA.

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.

For further details on summarization of AE data, please refer to "Analysis and Presentation of Adverse Event Data from Clinical Trials" (7) and "Handling of missing and incomplete AE dates" (3).

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

An overall summary of AEs will be presented. This overall summary will comprise summary statistics for the class of AESIs.

CTP Section 5.2.6.1.4: *The following are considered as AESIs:*

- *Hepatic injury*
  A hepatic injury is defined by the following alterations of hepatic laboratory parameters:

- *An elevation of AST (aspartate transaminase) and/ or ALT (alanine transaminase) ≥3-fold ULN combined with an elevation of total bilirubin ≥2-fold ULN measured in the same blood sample, or*
- *Aminotransferase (ALT, and/ or AST) elevations ≥10 fold ULN*

The investigator had to classify on the eCRF whether an observed AE was an AESI or not.

According to ICH E3 (8), in addition to deaths and SAEs, "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).

The frequency of subjects with AEs will be summarised by treatment, primary SOC and preferred term. AEs which were considered by the investigator to be drug related will be summarised separately. Separate tables will also be provided for subjects with SAEs and subjects with AESIs. AEs will also be summarized by maximum intensity.

The SOCs and preferred terms within SOCs will be sorted by descending frequency over all treatment groups.

For disclosure of AE data on ClinicalTrials.gov, the frequency of subjects with non-serious AEs occurring with an incidence of greater than 5 % (in preferred terms) will be summarised by treatment, primary SOC and preferred term. The frequency of subjects with SAEs will also be summarised.

For disclosure of AE data in the EudraCT register, the frequency of AEs, the frequency of non-serious AEs with an incidence of greater than 5 % (in preferred terms) and the frequency of SAEs will be summarized.

For support of lay summaries, the frequency of subjects with drug-related SAEs will be summarized by treatment, primary SOC and preferred term.

7.8.2 Laboratory data

The analyses of laboratory data will be descriptive in nature and will be based on BI standards "Display and Analysis of Laboratory Data" (9).

Analyses will be based on normalised values, which mean 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.

Descriptive statistics of absolute values and change from baseline from laboratory parameters over time (see Section 6.7) will be provided. Frequency tables of changes between baseline and last value on treatment with respect to the reference range will be presented.

Unscheduled measurements of laboratory 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. Descriptive statistics will be calculated by planned time point based on the worst value of the subject at that planned time point (or assigned to that planned time point).

Possibly clinically significant abnormal laboratory values are only those identified either in the Investigator's comments or at the RPM at the latest. It is the Investigator's responsibility to decide whether a lab value is clinically significant abnormal or not. Standard or project-specific rules for flagging clinically significant values in an automated manner will not be applied in this study.

Clinically relevant findings in laboratory data will be reported as baseline conditions (prior to first administration of study treatment) or as AEs (after first administration of study treatment) if judged clinically relevant by the investigator, and will be analyzed as such.

7.8.3 Vital signs

The analyses of vital signs (blood pressure and pulse rate) will be descriptive in nature. Descriptive statistics of absolute values and change from baseline from vital signs over time (see Section 6.7) will be provided.

Unscheduled measurements of vital signs will not be included in the descriptive statistics and will only be listed.

Clinically relevant findings in vital signs data will be reported as baseline conditions (prior to first administration of study treatment) or as AEs (after first administration of study treatment) if judged clinically relevant by the investigator, and will be analyzed as such.

7.8.4 ECG

Abnormal findings in ECG 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.

7.8.5 Others

Physical examination findings will be reported as relevant medical history/ baseline condition (if a condition already exists before first administration of study treatment) or as AE (if condition emerges after first administration of study treatment) and will be summarized as such. No separate listing or analysis of physical examination findings will be prepared.

8. REFERENCES

1	*CPMP/ICH/363/96*: "Statistical Principles for Clinical Trials", ICH Guideline Topic E9; Note For Guidance on Design, Conduct, Analysis and Evaluation of Clinical Trials, current version
2	*001-MCS-40-413_1.0:* "Identify and Manage Important Protocol Deviations (iPD)", current version; IDEA for CON
3	*KM Asset BI-KMED-BDS-HTG-0035:* "Handling of missing and incomplete AE dates", current version; KMED
4	*001-MCS-36-472_RD-01*: "Noncompartmental Pharmacokinetic / Pharmacodynamic Analyses of Clinical Studies", current version; IDEA for CON
5	*001-MCS-36-472_RD-03*: "Description of Analytical Transfer Files and PK/PD Data Files", current version; IDEA for CON
6	*KM Asset BI-KMED-BDS-HTG-0045:* "Standards for Reporting of Clinical Trials and Project Summaries", current version; KMED
7	*KM Asset BI-KMED-BDS-HTG-0066:* "Analysis and Presentation of Adverse Event Data from Clinical Trials", current version; KMED
8	*CPMP/ICH/137/95*: "Structure and Content of Clinical Study Reports", ICH Guideline Topic E3; Note For Guidance on Structure and Content of Clinical Study Reports, current version
9	*KM Asset BI-KMED-BDS-HTG-0042: "*Display and Analysis of Laboratory Data", current version; KMED

9. ADDITIONAL SECTIONS

Not applicable as no additional information is needed.

10. HISTORY TABLE

Table 10: 1 History table

Version	Date (DD-MMM-YY)	Author	Sections changed	Brief description of change
1	**05-FEB-21**	[redacted]	None	This is the final TSAP