Senhwa Biosciences
Protocol #: CX-4945-07
IQVIA Study #: UYA26114

A Phase I, Multi-Center, Open-Label, Treatment Duration Increment, Expansion, Safety, and Pharmacodynamic Study of CX-4945 Administered Orally Twice Daily to Patients with Advanced Basal Cell Carcinoma

Statistical Analysis Plan, version 1.0

Document last saved: 1-May-2023 5:12 PM

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List of Abbreviations and Definitions of Terms

Abbreviation	Definition
ADaM	Analysis data model
AE	Adverse event
ATC	Anatomical-therapeutic-chemical classification
BCC	Basal cell carcinoma
BID	Twice daily
BMI	Body mass index
CFR	Code of Federal Regulations
CR	Complete response
CRA	Clinical Research Associate
CRF	Case report form, paper or electronic
CRO	Contract research organization
CSR	Clinical study report
CTCAE	Common terminology criteria for adverse events
DLT	Dose limiting toxicity
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
Hh	Hedgehog
mBCC	Metastatic basal cell carcinoma
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
ORR	Objective response ratio
PT	Preferred Term
RDI	Relative dose intensity
RECIST	Response Evaluation Criteria in Solid Tumors
RP2D	Recommended Phase II Dose
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
SDTM	Study Data Tabulation Model
SOC	System organ class
TEAE	Treatment-emergent adverse event
WHO-DD	World Health Organization – Drug Dictionary

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study Protocol version 6.0 dated 06 April 2022.

This document provides additional details concerning the statistical analyses outlined in the protocol and reflects any changes to the protocol from any amendments. This plan will not repeat all the definitions given in the protocol but will provide further details of the summaries and analyses planned therein. Any deviations from the analysis plan, including any after the time of database lock, will be documented as such in the study report.

2. STUDY OBJECTIVES

Primary Objective: The primary objective of this study is to determine the recommended phase II dose (RP2D) and schedule of CX-4945 when administered orally twice daily for 28 consecutive days, in a 4-week (28 days) cycle, in patients with locally advanced or metastatic basal cell carcinoma (BCC).

Secondary Objectives:

- To establish the safety and tolerability of CX-4945 in this patient population.
- To assess preliminary evidence of antitumor effects in this patient population by documentation of objective responses using standardized criteria.
- To evaluate the effect of CX-4945 treatment on the Hedgehog (Hh) signaling pathway using qRT-PCR in tissue from patients with locally advanced BCC obtained at baseline and following CX-4945 treatment.

3. STUDY DESIGN

This is an open-label, multicenter, treatment-duration-increment Phase I run-in study followed by two expansion cohorts in patients with advanced basal cell carcinoma, to evaluate the safety, pharmacodynamic and preliminary antitumor activity of CX-4945. All patients will receive CX-4945 until evidence of progression, intolerable toxicities most probably attributable to CX-4945, or withdrawal from the study.

This study population will consist of patients ≥ 18 years old with a histologically confirmed diagnosis of advanced BCC (metastatic BCC [mBCC] or locally advanced BCC defined as follows) which has progressed on smoothened inhibitor or that are intolerant to smoothened inhibitor. Patients with mBCC are required to have histologic confirmation of a distant BCC metastasis (e.g., lung, liver, lymph nodes, or bone). Patients with locally advanced BCC are required to have disease that is considered inoperable or to have a medical contraindication to surgery. Patients with nevoid BCC syndrome (Gorlin syndrome) may enroll in this study but must meet the criteria for locally advanced or metastatic disease listed above.

In the phase I treatment-duration-increment part of the study, the 28-day continuous dosing of CX-4945 [1000 mg twice daily] will be explored. Dose cohort will initially include a minimum of 3 patients. A standard 3+3 design will be used.

- If no DLTs are seen in the 3 patients, the treatment-duration-increment part will be closed and the expansion cohorts will be opened.

- If 1 patient out of 3 experiences a DLT, up to 3 additional patients will be recruited (for a maximum of 6). If there are < 2/6 patients with DLT, this will be declared the dose for the Recommended Phase II Dose (RP2D), Phase I will be closed and the expansion cohorts will be opened.

- If 2 out of 3, or 2 out of 6, patients experience DLT, the previous Phase I oral dosing regimen of 1000 mg BID (total daily dose 2000 mg) for 21 days followed by 7 days of rest will be selected for the expansion cohorts.

The expansion cohorts will include 10 patients with locally advanced BCC and 10 patients with metastatic BCC.

During the treatment-duration-increment part, the first patient enrolled at the 28-day continuous dosing schedule must receive ≥ 75% planned doses with no observed DLTs before a second patient and a third patient are treated one week apart in that cohort. If no patient in the cohort experiences a DLT after the completion of Day 28 of the final patient in the cohort, then the Expansion Cohorts may proceed with the 28-day continuous dosing schedule.

Patients that have experienced a DLT may be offered the option to continue at the previous Phase I oral dosing regimen of 1000 mg bid (total daily dose of 2000 mg) for 21-day followed by 7 days of rest if this is considered safe by the Investigator and the Sponsor.

4. HARDWARE AND SOFTWARE

Statistical analysis will be performed following IQVIA Biotech standard operating procedures and on the IQVIA Biotech computer network. All statistical analysis will be performed using SAS Version 9.4 or later with program code prepared specifically for the project by qualified IQVIA Biotech statisticians and SAS programmers.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). Datasets will be created and taken as input to validated SAS programs to generate report-ready tables, listings, and figures. Each output display will show the names of the data sets and SAS program used to produce it.

5. DATABASE CLOSURE

After completion of all data review procedures, validation of the project database, and approval of the data review document by the study sponsor, the clinical database will be closed. Any change to the clinical database after this time will require written authorization, with explanation, by the Sponsor and the IQVIA Biotech Biostatistician.

6. SAMPLE SIZE DETERMINATION

In the treatment-duration-increment part of the study, a 3+3 study design will be utilized, therefore approximately 3-6 patients will be enrolled to define the RP2D.

In the expansion part of the study, a total sample size of 20 patients is proposed; 10 patients with local advanced BCC and 10 patients with metastatic BCC. Assume that CX-4945 is of no interest if its true response is 5% or lower, the proposed sample size for each sub-population will provide an 80% confidence interval of (5.5%, 45.0%) given that there are 2 responses out of the 10 patients. This would provide adequate evidence to suggest that additional studies with this agent may be warranted.

10 patients with metastatic BCC were planned in the expansion part of the study, but only 2 were enrolled due to early termination.

7. ANALYSIS POPULATIONS

The following analysis sets/populations will be used in this trial:

- **Safety population:** All enrolled patients who receive any amount of study drug. Unless otherwise noted, all safety analyses will be performed using Safety population.

- **Dose determining population:** All patients treated in the Phase 1 treatment-duration-increment part of the study. The dose determining population will be used to determine the primary outcome of the study, the RP2D dose.

- **Efficacy population**: All patients who are treated in the treatment-duration-increment cohort or the expansion cohort and whose pathologist's interpretation of baseline biopsy is consistent with BCC. Patients without interpretable baseline tissue, as determined by the pathologist, or by pathology report from the study site documenting a pathologist's determination of BCC will be excluded from the Efficacy population. Such patients' efficacy data will be presented in by-subject listings but excluded from all summary analyses. Objective response will be assessed separately for patients with mBCC vs. locally advanced BCC.

- **Relative Dose Intensity (RDI) population:** All patients treated in the expansion cohort including those who complete the protocol-defined treatment or discontinue treatment due to adverse events or for disease progression. Patients who are discontinued for any reason other than for adverse events or for disease progression will not be included in the relative dose intensity assessment. The RDI population will be used for the assessment of relative dose intensity defined for each cycle.

For some objectives (pharmacodynamics, biomarker parameters) a subgroup of patients of the efficacy population with respective baseline and post-baseline measurements will be used as described in section 11.9.1 below.

8. HANDLING OF MISSING DATA

Missing data will not be replaced with imputed values.

9. INTERIM ANALYSIS

No interim analysis is planned for this study.

10.DATA CONVENTIONS FOR ANALYSIS

10.1General Statistical Principles

All statistical processing will be performed using SAS® unless otherwise stated. Any statistical tests will be two-tailed at significance level of 0.05 unless otherwise specified.

All observed and derived variables (e.g., change from baseline, percentage change from baseline, and response status) used in the summaries of analyses will be presented in by-subject listings. Unless otherwise noted, the data will be sorted first by treatment assignment, then by subject number and then by date within subject number.

Efficacy and safety results will be summarized descriptively. Categorical parameters will be summarized by the number and percentage of subjects in each category. Denominators for percentages will be appropriate to the purpose of the analysis. Percentages will typically be presented to one decimal (Note: 0% and 100% will be in integer format). Continuous parameters will be summarized as number of subjects, mean, standard deviation (SD), median, minimum, and maximum.

10.2Study Day

Day 1 is defined as the date of first study drug administration. Study day is calculated relative to the date of Day 1. For subjects who did not have a recorded date of first study drug administration, study day will not be calculated.

10.3Baseline and Change from Baseline

Baseline is defined as the last non-missing assessment prior to the first administration of study drug. Change from baseline is defined as post-baseline value minus baseline value unless otherwise specified. Percent change from baseline is (Change from baseline / Baseline) * 100%.

10.4Analysis Visit Window

Results will be summarized according to the visit as recorded in the eCRF. No visit windows will be applied.

10.5Multiple Comparisons

Not applicable. There will be no formal hypothesis testing.

11.STATISTICAL EVALUATION

11.1Subject Disposition

The number and percentage of subjects screened, enrolled, included in key analysis populations, completing the study, and withdrawing from the study (together with the reasons for withdrawal) will be summarized using frequencies and percentages, overall and by cohort (treatment-duration-increment, expansion).

A by-subject listing will show all subjects enrolled and their disposition.

The number of days in the study (date of study completion / discontinuation minus date of Day 1 plus 1) will be summarized descriptively, overall and by cohort (treatment-duration-increment, expansion).

11.2Protocol Deviation

Protocol deviations will be logged throughout the study and classified as minor or major. Major protocol deviations will be summarized for all enrolled patients.

All protocol deviations will also be listed by subject.

11.3Demographic and Baseline Characteristics

Demographics and baseline characteristics will be summarized separately in mBCC and locally advanced BCC groups as well as overall for the Safety and Efficacy populations. The following demographic and baseline variables will be included:

- Age (years)
- Gender
- Race
- Ethnicity
- Weight (kg)
- Height (cm)
- BMI (kg/m^2)
- ECOG performance status

11.4Disease History

For the summary of BCC history, the following will be summarized separately in mBCC and locally advanced BCC groups and listed:

- Time since diagnosis (calculated as year of informed consent – year of initial diagnosis)
- BCC variant (nodular, superficial, infiltrative, basosquamous, other)
- Gorlin's syndrome (Y, N)

11.5Prior Therapy

Prior BCC therapy will be listed in three separate listings: (i) radiotherapy, (ii) systemic therapy, and (iii) anti-cancer surgery.

The summary of prior **radiotherapy** will include a summary of radiotherapy locations, including all locations recorded for each subject.

The summary of prior **systemic therapy** will include the total number of systemic therapies, the therapy type(s), and the time between end of last treatment to start of study treatment, and the best response after each treatment up to and including the last recorded.

The summary of prior **anti-cancer surgery** will include the time between the last surgery to start of study treatment and reason for surgery.

All summaries will be provided separately in mBCC and locally advanced BCC patients as well as overall.

11.6Study Medication Exposure

The following parameters of study drug exposure will be summarized for the RDI population:

- Cumulative dose (g), calculated as total number of capsules taken per subject diary* 0.2g, for each cycle and overall.
- Dose intensity (g/day, calculated as [cumulative dose (g) / duration of dosing (days)]), defined for each cycle
- Planned dose intensity (g/day, 1000mg BID=2g/day), defined for each cycle
- Relative dose intensity (% of planned, calculated as [dose intensity / planned dose intensity] *100), defined for each cycle

Cumulative dose will also be summarized for the Safety population.

11.7Prior and Concomitant Medications

Prior (within the previous 7 days and with stop dates prior to first dose of study drug) and concomitant (ongoing or with stop dates on or after first dose of study drug) medications will be presented for the safety population in a by-subject listing. If the medication is ongoing or the stop year is missing, the medication will be considered as received for the entire duration of the study. Medications will be coded using WHO-DD terminology.

For the determination of prior vs concomitant medications, the following rules regarding the stop date will be applied:

- If only year was recorded, and it is before Baseline, it is a prior medication; if year is same or after Baseline, it is assumed to be a concomitant medication.

- If day is missing, but month and year are before Baseline, it is a prior medication; if month and year are the same as Baseline, it is assumed to be a concomitant medication; if month and year are after Baseline, it is a concomitant medication.

- If start date is after Baseline, it is a concomitant medication regardless.

Concomitant medications will be summarized by WHO-DD Anatomical-Therapeutic-Chemical (ATC) classification level 4 or highest level available and preferred term (PT).

Use of dispensed anti-emetics and use of dispensed loperamide will be listed in separate listings.

11.8Medical History and Concurrent Procedures

Medical history (including previous and ongoing medical conditions) will be coded using MedDRA (version 23.0) and summarized by System Organ Class (SOC) and preferred term (PT).

11.9Efficacy Endpoints

11.9.1 Primary Efficacy Endpoints

The efficacy endpoints include the following:

- **Best Overall Response**: Assessed separately for patients with mBCC and with locally advanced BCC as a function of radiographic, photographic, and pathologic review (Appendices B, C, G and H of the protocol) as described below.

  For patients with mBCC: Overall Response will be assessed using the Response Evaluation Criteria in Solid Tumors (RECIST).

  For patients with locally advanced BCC: Overall response will be assessed using a composite response endpoint that incorporates externally visible tumor dimension and tumor ulceration, as well as RECIST for lesions with a RECIST-measurable component.

  Patients will be categorized as Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD), and Not Evaluable (NE) in Overall Response at each assessment.

- **Objective Response**: Defined as a Complete Response (CR) or Partial Response (PR) in Overall Response determined on two consecutive assessments ≥ 4 weeks apart.

  In patients with locally advanced BCC achieving a CR or PR, tumor biopsies will be used in the final determination of CR. CR is defined as absence of residual BCC on biopsy; PR is defined as presence of residual BCC on biopsy.

- Analysis of the changes in *Gli1* expression will be conducted by the OncoCyte Corporation (formerly Insight Genetics) and a separate report will be prepared. Thus detailed analysis is not included in this SAP.

11.9.2 Other Efficacy Endpoints

- **Progression Free Survival (PFS):** Defined as the time from the date of the first dose of study drug until the date of progressive disease or death from any cause, whichever occurs first. PFS will be censored as follows:

    - Patients who had no event (i.e., they did not die or have PD) will be censored at the date of their last tumor assessment.
    - Patients with no baseline assessment will be censored at the date of the first dose.
    - Patients who started a new anti-cancer therapy prior to documented PD or death will be censored at the last tumor assessment prior to initiation of new anti-cancer therapy.

- **Duration of Response (DOR):** Defined as the time from the date of first documented response (CR or PR) until the date of progressive disease or death from any cause, whichever occurs first, after achieving response. DOR will be censored as follows:

    - Patients who had no event (i.e., they did not die or have PD) will be censored at the date of their last tumor assessment.
    - Patients who started a new anti-cancer therapy prior to documented PD or death will be censored at the last tumor assessment prior to initiation of new anti-cancer therapy.

- **Duration of Stable Disease (DSD):** Defined as the time from the date of first documented Stable Disease (SD) response until the date of progressive disease or death from any cause, whichever occurs first, after achieving SD response. DSD will be censored as follows:

    - Patients who had no event (i.e., they did not die or have PD) will be censored at the date of their last tumor assessment.
    - Patients who started a new anti-cancer therapy prior to documented PD or death will be censored at the last tumor assessment prior to initiation of new anti-cancer therapy.

- **Disease Control Rate (DCR):** Defined as the percentage of patients who have achieved CR, PR, or SD lasting at least 6 months.

- **Duration of Disease Control (DDC):** Defined as the time from the date of first documented response (CR or PR) or Stable Disease (SD) until the date of progressive disease or death from any cause, whichever occurs first, for patients with CR, PR or SD lasting at least 6 months. DDC will be censored as follows:

    - Patients who had no event (i.e., they did not die or have PD) will be censored at the date of their last tumor assessment.

- Patients who started a new anti-cancer therapy prior to documented PD or death will be censored at the last tumor assessment prior to initiation of new anti-cancer therapy.

- **Rate of patients with CR+PR+SD (regardless of duration):** Defined as the percentage of patients who have achieved CR, PR, or SD.

- **Duration of CR+PR+SD:** Defined as the time from the date of first documented response (CR or PR) or Stable Disease (SD) until the date of progressive disease or death from any cause, whichever occurs first, for patients with CR, PR or SD. The duration will be censored as follows:

    - Patients who had no event (i.e., they did not die or have PD) will be censored at the date of their last tumor assessment.
    - Patients who started a new anti-cancer therapy prior to documented PD or death will be censored at the last tumor assessment prior to initiation of new anti-cancer therapy.

11.10 Efficacy Analyses

11.10.1Primary Efficacy Analyses

The primary endpoints will be assessed in the Efficacy population, overall and separately for patients with mBCC and patients with locally advanced BCC.

The objective response rate (ORR) will be calculated as the number of patients satisfying the OR criteria divided by the number of subjects in the Efficacy population. Patients without at least one post-baseline response assessment will be treated as non-responders. Further, patients who experience progressive disease but continue treatment under the protocol and experience partial or complete response in a subsequent tumor assessment, will be considered partial or complete responders. A continuity-corrected 95% confidence interval based on the normal approximation will accompany each ORR.

Complete response rates (CRR) will be summarized in parallel fashion to ORR.

11.10.2Other Efficacy Analyses

PFS will be analyzed using the Kaplan-Meier method in the Efficacy population, separately for patients with mBCC and patients with locally advanced BCC.

Summary statistics from the Kaplan-Meier distribution will be determined, including the median and estimates at 3, 6, 9, 12 months. These statistics will be provided as point estimates with 95% confidence intervals.

DOR summary will include at least median (in months), range and patients (n, %) with observed DOR for at least 6 months.

DSD summary will include at least median, range, min, max and patients (n, %) with observed SD for at least 6 months.

DCR summary will include at least median, range, min, max and patients (n, %) with observed DCR for at least 6 months.

Summary of patients with CR+PR+SD (regardless of duration) will include at least median, range, min, max and patients (n, %) with observed CR+PR+SD.

11.10.3Subgroup Analyses

Not applicable.

11.11 Safety Analysis

Safety will be summarized over the Safety population unless indicated otherwise.

11.11.1Recommended Phase 2 Dose (RP2D)

The primary endpoint for this study is the determination of RP2D in the 28-day continuous dosing of CX-4945 [1000 mg twice daily] of the phase I treatment-duration-increment part of the study, as following:

- If no DLTs are seen in the 3 patients, the treatment-duration-increment part will be closed and the expansion cohorts will be opened. This will be declared the dose for the RP2D.

- If 1 patient out of 3 experiences a DLT, up to 3 additional patients will be recruited (for a maximum of 6). If there are < 2/6 patients with DLT, this will be declared the dose for the RP2D, Phase I will be closed and two expansion cohorts will be opened.

- If 2 out of 3, or 2 out of 6, patients experience DLT, the previous Phase I oral dosing regimen of 1000 mg BID (total daily dose 2000 mg) for 21 days followed by 7 days of rest will be selected for the expansion cohorts.

The procedures and rules to determine the RP2D are given in Section 9.1 of the protocol and as described above. Because of the small number of patients involved in this endpoint, no summaries will be generated. The determination of the RP2D in the RP2D population (see Section 7) will be described textually.

11.11.2Dose Limiting Toxicity (DLT)

Dose limiting toxicity (DLT) will be defined as any of the following drug related adverse events occurring during Cycle 1 (first 28 days of dosing):

- Grade 3 or 4 non-hematologic toxicity (excluding inadequately managed nausea and vomiting, alopecia or grade 3 fatigue lasting < 7 days),
- Grade 4 myelosuppression ≥ 7 days, febrile neutropenia or ≥ grade 3 thrombocytopenic bleeding,

- Other toxicity of concern to the investigators including toxicities requiring delays ≥ 14 days.

All DLTs will be listed and summarized by cohort (treatment-duration-increment, expansion) and overall for the Safety population.

11.11.3Adverse Events

Adverse event terms will be coded using Medical Dictionary for Regulatory Activities (MedDRA) dictionary. A treatment-emergent AE (TEAE) is defined as an AE that starts or worsen on or after the date of the first dose of study medication. Adverse events that have missing onset dates will be considered to be treatment emergent, unless the stop date is known to be prior to the first administration of the study medication. If the AE onset date is partial, the date will be compared as far as possible with the date of first dose of study medication. Adverse events will be assumed to be treatment-emergent, unless there is clear evidence (through comparison of partial dates) to suggest that the AE started prior to the first dose of study medication. All TEAE swill be mapped to thesaurus terms and graded according to the NCI CTCAE, version 5.0.

All AEs will be listed by subject, detailing the verbatim term given by the investigator, the preferred term (PT), system organ class (SOC), onset date, end date, CTCAE Grade, outcome, relationship to study drug, action taken with study drug, other action taken, seriousness and criteria for seriousness. Serious AEs (SAEs) and TEAEs leading to study discontinuation will also be listed separately.

The following TEAE summaries will be produced by cohort (treatment-duration-increment, expansion) and overall:

- An overall summary of safety will summarize the numbers (and percentages) of patients with the following:

    - Any TEAEs and serious adverse event (SAE)
    - AEs related to study drug
    - SAEs related to study drug
    - AEs of Clinical Interest
    - DLTs
    - Who discontinued study drug due to at least one AE (regardless of causality, and related to each study drug)
    - AEs leading to death

- Separate summaries of TEAEs by SOC and PT, subset as follows:

    - All AEs
    - AEs related to study drug. Related AEs will include AEs with a drug relationship of “Related” recorded on CRF.
    - All SAEs
    - SAEs related to study drug
    - All Grade 3 or above AEs

  - Grade 3 or above AEs related to study drug
  - All AEs in at least 10% of subjects
  - AEs in at least 10% of subjects related to study drug
  - All AEs leading to discontinuation of study drug
  - All AEs leading to dose interruptions
  - All AEs leading to dose modifications
  - All AEs leading to death, overall, while on study and during the 3-month follow-up period

- All AEs by SOC, PT and CTCAE toxicity grade

- All AEs by SOC, PT and action taken with study drug

- All AEs by PT

If a patient has multiple occurrences of an AE, the strongest level of relationship to study drug and the worst toxicity grade a patient experiences for a given AE will be used in these tables. Further, if the toxicity grade is missing, the event will be reported as 'unknown' in the summary tables. Likewise, if causality data is missing, 'unknown' will be reported.

11.11.4Clinical Laboratory Testing

Clinical laboratory values will be reported as complete listings of individual subject data. All laboratory values will be classified as normal, low, or high based on normal ranges supplied by the laboratory. Clinical laboratory values outside of normal range will be listed in a separate by-subject listing.

Absolute values and changes from baseline of clinical laboratory data (hematology, chemistry, and continuous urinalysis parameter) will be summarized descriptively. Changes in out-of-range reference flags from Baseline to post-baseline visits in clinical laboratory data will also be summarized using shift tables.

Vitamin D assessments, pregnancy test results will be presented in separate by-subject listings.

11.11.5Vital Signs

Vital signs including body weight, blood pressure (systolic and diastolic), pulse rate, respiratory rate, and body temperature will be presented in a by-subject listing by visit. Absolute values and change from baseline value will be summarized by treatment group using descriptive statistics.

11.11.6Electrocardiogram (ECG)

ECG data measured at Screening will be presented in a by-subject listing.

11.11.7Physical Examination

Physical examination results will be captured on eCRF but will not be presented in tables or listings.

11.11.8ECOG Performance Status

The Eastern Cooperative Oncology Group (ECOG) status of patients will be listed and summarized using frequency counts and percentages by visit.

12.CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

This SAP reflects the analysis plan outlined in the study protocol without significant change. Any analysis changes or additional analysis not specified in this SAP will have the status of unblinded and exploratory investigations.

13.HEADINGS

Each page of the analysis will show the sponsor's name, the investigational product, and the protocol number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

14.ARCHIVING AND RETENTION OF DOCUMENTS

After finalization of the analysis, the following will be archived at IQVIA Biotech and/or with the study sponsor:

- SAP and any amendments
- All SAS code used in the project for statistical analysis, report tables generation, and analysis data set creation
- Tables, listings and figures as included in the clinical study report
- SAS study data tabulation model (SDTM) and analysis datasets