Statistical Analysis Plan

Study Title:	A Single-center, Randomized, Double-blind, Multiple Ascending Dose, Placebo-controlled Phase Ib/IIa Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics and Early Pharmacodynamics of BGT-002 Tablets in Subjects with NASH
Protocol No. (Version No./Date):	BGT-002-004 (V2.0/2023-10-09)
Sponsor:	Burgeon Therapeutics Co., Ltd.
Statistical Unit:	Linzhi (Beijing) Technology Co., Ltd.
Version No.:	V1.0
Version Date:	2024-04-16

Table of Contents

List of Abbreviations and Definition of Terms

Abbreviation	Definition
AE	Adverse Events
ALT	Alanine Aminotransferase
ANA	Antinuclear antibody
AST	Aspartate aminotransferase
AUC	Area under plasma concentration-time curve
AUC_{ss}	Area under plasma concentration-time curve at steady state
β-HB	β-hydroxybutyrate
BMI	Body mass index
CAP	Controlled Attenuation Parameter
CI	Confidence interval
CK18	Cytokeratin 18
CL_{ss}/F	Clearance at steady state
C_{max}	Maximum plasma concentration
$C_{max, ss}$	Maximum plasma concentration at steady state
$C_{min, ss}$	Minimum plasma concentration at steady state
CRF	Case report form
CTCAE	Common Terminology Criteria for Adverse Events
CV	Coefficient of variation
FAS	Full analysis set
FGF21	Fibroblast growth factor 21
hsCRP	High-sensitivity C-reactive protein
IP10	IFN-γ-inducible protein 10
LSM	Liver Stiffness Measurement
LDL	Low-density lipoprotein cholesterol
MedDRA	Medical Dictionary for Regulatory Activities
MRI-PDFF	MRI-Proton Density Fat Fraction
NASH	Non-alcoholic steatohepatitis
PD	Pharmacodynamics
PDS	Pharmacodynamic analysis set
PK	Pharmacokinetics
PKS	Pharmacokinetic set
PT	Preferred term
R_{ac}	Accumulation ratio
SAE	Serious Adverse Events
SAP	Statistical Analysis Plan
SOC	System Organ Class
SS	Safety Set
$t_{1/2}$	Elimination half-life
TG	Triglyceride
TIMP1	Tissue Inhibitor of Metalloproteinase-1
T_{max}	Time to maximum plasma concentration
λ_z	Terminal Elimination Rate Constant

1. Introduction

This Statistical Analysis Plan (SAP) is prepared based on the clinical study protocol "A Single-center, Randomized, Double-blind, Multiple Ascending Dose, Placebo-controlled Phase Ib/IIa Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics and Early Pharmacodynamics of BGT-002 Tablets in Subjects with NASH" (Version No./Version Date: V2.0/2023-10-09) and CRF (Version No./Date: V2.0/2023-10-23). This SAP will fully state the methods of analysis and presentation of the data in this protocol.

2. Objectives

2.1. Primary Objective

To evaluate the safety and tolerability of BGT-002 Tablets in subjects with NASH after oral administration;

2.2. Secondary Objectives

1) To evaluate the pharmacokinetics (PK) of BGT-002 Tablets in subjects with NASH after oral administration;

2) To evaluate the effect of BGT-002 on lipid metabolism in subjects with NASH;

3) To evaluate the effect of BGT-002 on biochemical indicators related to liver function in subjects with NASH.

2.3. Exploratory Objective

To evaluate the biomarker profile of BGT-002 in subjects with NASH.

3. Study Design

3.1. Overall Study Design

This study is a single-center, randomized, double-blind, multiple ascending doses (MAD), placebo-controlled phase Ib/IIa clinical trial of BGT-002 Tablets in subjects with NASH to evaluate the safety, tolerability, pharmacokinetics (PK) and early pharmacodynamics (PD) of BGT-002 Tablets.

The number of subjects: A total of 48–60 subjects are planned to be enrolled in this study.

3.2. Dose Group Design

It is originally planned to set 3-4 dose groups in this study, and the dose ascending design

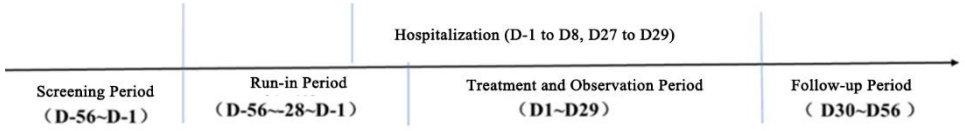
is as follows: 50 mg, 75 mg, 100 mg, and 125 mg (alternative). In this trial, it is planned to start with 50 mg as the lowest dose group. During the study, whether to continue to escalate to a higher dose group or adjust the dose ascending ratio will be determined based on available data.

As of September 13, 2023, based on the results of the completed interim analysis for three dose groups (50 mg, 75 mg and 100 mg), after discussion, the Sponsor and investigator decided to add 150 mg and 200 mg (alternative) groups for a 28-day continuous administration study, with 3 sentinels in the 150 mg and 200 mg (alternative) groups, respectively (2 subjects in the test group, and 1 subject in the placebo group) and observe for 8 days. If the safety is good, the remaining subjects will continue to be enrolled in this dose group (7 subjects in the test group and 2 subjects in the placebo group).

Dose (mg)	50	75	100	150	200 (alternative)
Number of Subjects (Study Drug + Placebo)	9+3	9+3	9+3 (Male:female = close to 1:1)	9+3	9+3

Each dose group will randomly include 12 screened eligible subjects with NASH, with 9 taking the study drug orally and 3 taking the placebo orally. A total of 48-60 subjects will be included in the study. Whether to conduct the dose expansion study will be based on the results of the dose ascending phase.

Study Schedule:



3.3. Randomization Scheme

The subject randomization codes will be designed by statisticians independent of the study. During the trial, enrollment numbers will be assigned according to the randomization schedule, and subjects in each dose group will be randomly assigned to receive BGT-002 or placebo.

The randomization schedule will be prepared by the randomization statistician before the start of the study. Screened eligible subjects will be assigned with subject numbers in ascending order of screening number, and the investigator will ensure that the corresponding drug is given to the subjects according to the numbers.

3.4. Blinding

The study drug and placebo will be provided by the sponsor or its designated unit to ensure that the shape and weight of the placebo are similar to those of the study drug. The study drug and placebo in each treatment group will be blinded by the unit designated by the sponsor, and the statisticians will randomize the subjects into the study drug group or placebo group.

3.5. Unblinding

Emergency unblinding: When it is really necessary to unblind in an emergency, the Principal Investigator (PI) and Sponsor should be consulted. The authorized investigator can use the emergency letter to unblind with the consent of the PI and Sponsor.

Unblinding regulations: This trial will involve one unblinding. After the database is locked, the unblinding will be carried out with the consent of the study site and the Sponsor, and relevant personnel who keep the blinding codes will submit the randomization information of the trial to the statistical department for statistical analysis.

4. Criteria for Evaluation

4.1. Tolerability and Safety Evaluation Indicators

The safety and tolerability of BGT-002 in subjects after administration will be evaluated.

Adverse events (AEs) throughout the study will be evaluated and graded according to CTCAE 5.0.

The indicators will include symptoms and physical examination, clinical laboratory tests (hematology, coagulation function, blood chemistry and urinalysis), vital signs (blood pressure, pulse, respiration and body temperature) and 12-lead ECG.

C-QTc study: To investigate the effect of BGT-002 in 75 mg, 100 mg, 150 mg and 200 mg (alternative) dose groups on QT/QTc interval in subjects, a C-QTc study will be conducted for 36-48 subjects on D1 and D28.

4.2. PK Variables

Evaluation of PK parameters for BGT-002 and its metabolites (if applicable) will include:

Evaluation of PK parameters on Day 1 (D1): C_{max}, T_{max}, $AUC_{0\text{-}24h}$, etc.;

Evaluation of steady-state PK parameters (D28): $C_{max,ss}$, $T_{max,ss}$, $AUC_{0\text{-}24h,ss}$, CL_{ss}/F, $C_{min,ss}$,

R_{ac}, etc.

4.3. PD and Exploratory Evaluation Indicators

Primary Efficacy Variables:

Changes from baseline in ALT, AST, BMI and blood lipid levels at Week 4 and Week 8;

Change from baseline in liver fat content measured by MRI-PDFF at Week 4 and Week 8;

Proportion of subjects with a relative reduction of at least 30% in liver fat content measured by MRI-PDFF at Week 4 and Week 8;

Secondary Efficacy Variables:

Changes from baseline in CAP and LSM at Week 4 and Week 8;

Exploratory Variables:

Changes from baseline in biomarkers (CK18, FGF21, IP10, hsCRP, TIMP1, β-HB) at Week 4 and Week 8.

5. Data Sets Analyzed

Full Analysis Set (FAS): Randomized subjects who received at least 1 dose of the study drug.

Safety Set (SS): Randomized subjects who received at least 1 dose of the study drug with safety data available.

Pharmacokinetics Set (PKS): Randomized subjects who received at least 1 dose of the study drug with at least one evaluable PK concentration data. The inclusion of subjects in the PKS will be determined on a case-by-case basis at the data verification meeting.

Pharmacodynamics Set (PDS): Randomized subjects who received at least 1 dose of the study drug with at least one valid PD evaluation data. The inclusion of subjects in the PDS will be determined on a case-by-case basis at the data verification meeting.

6. Statistical Methods

6.1. General Principles

Statistical analysis will be completed using SAS 9.4 or above, and PK parameters will be calculated using WinNonlin 8.3 or above. Measurement data will be statistically described using the number of subjects, mean, standard deviation, median, quartiles, minimum and

maximum. For some measurement data, coefficient of variation, geometric mean and geometric coefficient of variation will also be calculated; count data and ranked data will be statistically described using the frequency and percentage of each category or rank. Unless otherwise specified, missing values will not be included in the calculation of percentage.

In the statistical analysis, subjects who receive the placebo will be combined as a placebo group for analysis.

6.2. Data Processing Methods

6.2.1. Rounding of Data

Measurement data: The minimum and maximum will be rounded to the same decimal place as the original data, the mean, geometric mean, median and quartiles will be rounded to one more decimal place than the original data (in case of inconsistency, the most decimal places will be taken), the standard deviation will be rounded to 2 more decimal places than the original data, with a maximum of four decimal places retained, and the coefficient of variation, geometric coefficient of variation and percentage change will be rounded to 2 decimal places.

Count data: Percentages will be uniformly rounded to one decimal place and marked with a percentage sign, such as x (x.x%). The brackets are all brackets in English form. If the percentage of an item in a table is 100%, it will be marked as x (100%). If the frequency of an item in a table is 0, it will be marked as 0. Unless otherwise specified in the table, the number of missing subjects will not be included in the denominator for percentage calculation.

The confidence interval (CI) will be rounded to the same number of decimal places as its point estimate.

For *P* values, the *P* value 6.4 format in SAS will be used.

6.2.2. Handling of Missing Data

All data will be based on available observational data, and missing data will not be imputed; in case of outliers, the handling method will be determined through discussion at the Data Review Meeting.

6.2.3. Handling of Other Abnormal Data

In case of a vacancy, "missing" will noted in the shift table according to the statistical

tabulation rules. However, the raw data will be presented in the listings and no further processing of the data will be considered.

6.3. Study Subjects

6.3.1. Disposition of Subjects

- The flow chart for the disposition of subjects will be prepared
- The subjects screened, enrolled, screen failed/excluded, and reasons for screen failure/exclusion will be described in frequency and percentage
- The final status of enrolled subjects, major protocol deviations and each analysis data set were described by dose group in frequency and percentage
- The subjects screen failed/excluded, final status of enrolled subjects, early withdrawal subjects, protocol deviations and subjects excluded from the analysis set will be listed

6.3.2. Demographic and Other Baseline Characteristics

Based on FAS, the demographics and baseline characteristics of subjects will be summarized and analyzed by dose group, with the latest examination result before the first dose as the baseline.

- Demographics will include age, gender, ethnicity, baseline height, weight and BMI
- Baseline characteristics will include past/present medical history, smoking history, drinking history, allergic history, blood donation/transfusion history, clinical trial history, HbA1c, creatinine clearance rate, infectious disease screening, alcohol breath test, urine drug screen, ANA test, thyroid function, chest X-ray, abdominal B-scan ultrasonography (liver, gallbladder, spleen, pancreas and both kidneys), prior medications and prior non-drug therapies
- Medication history will be coded using ATC/DDD (Version 2023 or above)
- Medical history and non-drug therapy history will be coded using MedDRA (Version 26.0 or above)
- Demographics, past/present medical history, smoking history, drinking history, allergic history, blood donation/transfusion history, clinical trial history, HbA1c, creatinine clearance rate, infectious disease screening, alcohol breath test, urine drug screen, ANA test,

thyroid function, chest X-ray, abdominal B-scan ultrasonography, prior medications and prior non-drug therapies will be listed

6.3.3. Extent of Exposure

Based on FAS, the total number of study drug exposures, actual cumulative dose and treatment compliance of subjects will be summarized and analyzed by dose group.

- Total number of exposures = total number of study drug administrations
- Planned cumulative dose (mg) = total number of planned exposures × planned dose
- Actual cumulative dose (mg) = Sum of actual dose administered each time
- Treatment compliance (%) = (actual cumulative dose/planned cumulative dose) × 100%
- Treatment compliance will be statistically classified as <80%, 80%-120% and >120%
- Study drug administrations will be listed

6.3.4. Concomitant Medication/Non-Medication Therapy

Concomitant medications and concomitant non-drug therapies of subjects will be summarized and analyzed by dose group based on FAS.

- Concomitant medications will be coded using ATC/DDD (Version 2023 or above)
- Concomitant non-drug therapies will be coded using MedDRA (Version 26.0 or above)
- Concomitant medications and concomitant non-drug therapies will be listed

6.4. Analysis of Efficacy

6.4.1. Analysis of Plasma Concentrations

Based on PKS, the plasma concentrations of BGT-002 and its metabolites in subjects will be descriptively analyzed by dose group, visit and planned blood collection time point, with the number of subjects, mean, standard deviation, geometric mean, median, quartiles, maximum, minimum, coefficient of variation, and geometric coefficient of variation listed.

- When the plasma concentration is descriptively analyzed by visit and planned blood collection time point, plasma concentration values below the quantification limit (BQL) will

be treated as missing values, and concentration data beyond the window will not be included in the descriptive analysis of plasma concentration at the time point

- The mean plasma concentration (c)-time (t) curve (plasma concentration-time curve) will be plotted according to the planned blood collection time, and the individual plasma concentration-time curve will be plotted according to the actual blood collection time (actual blood collection time = actual blood collection date and time-actual administration date and time; the actual blood collection time before dosing is 0 h). For plasma concentration values below the quantification limit (BQL), those before reaching C_{max} will be treated as 0, while those after reaching C_{max} will be treated as missing values
- PK blood collection points: 0 h pre-dose (within 60 min pre-dose), 10 min (±0.5 min), 20 min (±0.5 min), 40 min (±1 min), 1 h (±1 min), 1.5 h (±1.5 min), 2 h (±1.5 min), 3 h (±3 min), 4 h (±3 min), 6 h (±6 min), 8 h (±6 min), 12 h (±12 min), and 24 h (±36 min) post-dose on D1; within 60 min pre-dose on D8, D15, D22, D26, and D27; 0 h pre-dose (within 60 min before dosing), 10 min (±0.5 min), 20 min (±0.5 min), 40 min (±1 min), 1 h (±1 min), 1.5 h (±1.5 min), 2 h (±1.5 min), 3 h (±3 min), 4 h (±3 min), 6 h (±6 min), 8 h (±6 min), 12 h (±12 min), and 24 h (±36 min) post-dose on D28; for blood collection points of the 100 mg, 150 mg and 200 mg (alternative) groups, 72 h (±1 h, D31), 168 h (±2 h, D35), 240 h (±2 h, D38), and 312 h (±2 h, D41) post-dose on D28 are added
- The PK blood sample collection will be listed

6.4.2. Analysis of PK Variables

Based on PKS, the PK parameters of subjects will be descriptively analyzed by dose group and visit, with the number of subjects, mean, standard deviation, geometric mean, median, quartiles, maximum, minimum, coefficient of variation, and geometric coefficient of variation listed. Non-parametric test will be used to compare T_{max} and $T_{max,ss}$ in each dose group. The power model will be used to assess the dose proportionality between the main PK parameters (C_{max}, AUC_{0-24h}, $C_{max,ss}$, $AUC_{0-24h,ss}$) and administered dose, and trend charts related to main PK parameters and administered dose will be provided.

- PK indicators: See the table below for details of C_{max}, T_{max}, AUC_{0-24h}, etc. Calculated according to the actual blood collection time (actual blood collection time = actual blood collection date and time - actual administration date and time; the actual blood collection time

before administration is 0 h). For plasma concentration values below the quantification limit (BQL), those before reaching C_{max} will be treated as 0, and those after reaching C_{max} will be treated as missing values

Category	Parameter	Definition
D1 PK Parameters	C_{max}	Maximum plasma concentration, obtained directly from the observed plasma concentration-time data.
	T_{max}	Time to maximum plasma concentration, obtained directly from the observed plasma concentration-time data.
	AUC_{0-24h}	Area under the plasma concentration-time curve from time zero to 24 h (calculation method: Linear up log down).
D28 PK Parameters	$C_{max,ss}$	Maximum plasma concentration at steady state, obtained directly from the observed plasma concentration-time data.
	$T_{max,ss}$	Time to maximum concentration at steady state, obtained directly from the observed plasma concentration-time data.
	$C_{min,ss}$	Minimum concentration over a dosing interval at steady state, obtained directly from the observed plasma concentration-time data.
	$AUC_{0-24h,ss}$	Area under the plasma concentration-time curve from time zero to 24 h at steady state (calculation method: Linear up log down).
	Cl_{ss}/F	Apparent clearance, Cl_{ss}/F = Dose/$AUC_{0-\tau,ss}$ (Dose is the corrected administered dose, and the correction formula is dose*(326.47/370.44)), for parent drug only.
	λ_z	Elimination rate constant, calculated as the slope of the terminal phase of the plasma concentration-time curve on a semi-log scale using a linear regression method. For 100 mg, 150 mg and 200 mg (alternative) groups only.
	$t_{1/2}$	Terminal elimination half-life, $t_{1/2}$ = ln2 / λ_z. For 100 mg, 150 mg and 200 mg (alternative) groups only.
	$R_{ac}[C_{max}]$	Accumulation ratio of C_{max}. $R_{ac}[C_{max}]$ = $C_{max,ss}$(multiple)/C_{max}(first).
	$R_{ac}[AUC_{0-24h}]$	Accumulation ratio of AUC. $R_{ac}[AUC]$ = $AUC_{0-24h,ss}$ (multiple)/AUC_{0-24h} (first).

Note: τ is the dosing interval. In this study, τ = 24 h.

- For the power model, log transformation will be performed based on PK parameter = $e^{\alpha}(dose)^{\beta}$, and the model after transformation will be ln(PK parameter) = $\alpha + \beta$ln(dose) + ε. The overall slope β, *i.e.* the exponent of the model, will be calculated to estimate its 90%CI.

- Evaluation criteria for the power model: If the 90% CI for β completely falls within the judgment interval, it can be considered that the PK parameter has dose proportionality. If the 90% CI of β falls completely outside the judgment interval, the PK parameter does not have dose proportionality in the given dose range. If the 90%CI of β partially overlaps with the acceptance interval, no definitive conclusion can be made within the given dose range.
- The judgment interval of the power model is $[1+\frac{\ln(\theta_L)}{\ln(r)}, 1+\frac{\ln(\theta_H)}{\ln(r)}]$. Where, r=H/L, H represents the highest dose administered and L represents the lowest dose administered; θ_H is the upper limit of confidence interval given based on statistical and experimental experience, and θ_L is the lower limit of confidence interval given based on statistical and experimental experience. In this study, $[\theta_L, \theta_H]$ is [0.5, 2].
- Non-parametric Kruskal-Wallis test will be used for T_{max} and $T_{max,ss}$ of each dose group
- PK parameters will be listed

6.4.3. Analysis of PD Variables

Based on PDS, PD indicators of subjects as well as changes and percentage changes from baseline will be descriptively analyzed by dose group and visit time point, with the latest test result before the first dose as the baseline.

- PD indicators: MRI-PDFF, CAP, LSM, BMI, ALT, AST, TG, LDL, and TC
- Visit time points include baseline, D29 and D56
- Change from baseline = PD indicator of each visit - baseline PD indicator; percentage change = change from baseline/baseline PD indicator × 100%
- The proportion of subjects with a relative reduction of at least 30% in liver fat content measured by MRI-PDFF will be listed
- The mean change-time curve and the histogram of mean percentage change from baseline will be plotted for PD indicators by visit time point
- The PD indicators of enrolled subjects will be listed

6.4.4. Analysis of Exploratory Variables

Based on PDS, exploratory indicators of subjects as well as changes and percentage changes from baseline will be descriptively analyzed by dose group and visit time point, with

the latest test result before the first dose as the baseline.

- Exploratory indicators: CK18, FGF21, IP10, hsCRP, TIMP1, and β-HB (the test indicators will be adjusted according to the actual condition of the testing unit)
- Visit time points include baseline, D29 and D56
- Change from baseline = exploratory indicator of each visit - baseline exploratory indicator; percentage change = change from baseline/baseline exploratory indicator × 100%
- The mean change-time curve and the histogram of mean percentage change from baseline will be plotted for exploratory indicators by visit time point
- The exploratory indicators of enrolled subjects will be listed

6.5. Analysis of Safety

6.5.1. Adverse Events

Based on SS, the number of subjects, number of events and incidence of AEs, AEs related to study drug, Grade ≥ 3 AEs, Grade ≥ 3 AEs related to study drug, SAEs, SAEs related to study drug and AEs leading to early withdrawal will be summarized by dose group; the relationship between AEs and the study drug, grade of AEs, measures taken for the study drug, measures taken for adverse events and outcome will also be summarized.

- AEs related to study drug refer to AEs judged as definitely, probably or possibly related to the study drug
- All the AEs will be coded using MedDRA v26.0 or above.
- The number of events, number of subjects and incidence of AEs and AEs related to study drug will be calculated by SOC/PT
- The number of events, number of subjects and incidence of AEs and AEs related to study drug will be calculated by SOC/PT and severity. If a subject experiences multiple AEs of different severities, the most severe one will be used for calculation
- The number of events, number of subjects and incidence of AEs, AEs related to study drug, Grade ≥ 3 AEs, Grade ≥ 3 AEs related to study drug, SAEs and SAEs related to study drug will be calculated by PT
- Time of onset (Day) = start date of AE - date of first dose + 1; duration (days) = end date of AE - start date of AE + 1

- AEs, AEs related to study drug, Grade ≥ 3 AEs, SAEs, AEs leading to early withdrawal and AEs with unknown outcomes (persistent, aggravated, death, unknown) will be listed

6.5.2. Laboratory Tests

Based on SS, the clinical significance of subjects' laboratory tests (hematology, blood chemistry, urinalysis and coagulation function) before and after administration will be summarized using a shift table (judgment on clinical significance will be made based on the worst result after administration). The subjects' laboratory test results and changes from baseline will be descriptively analyzed by visit time point, with the latest test result before the first dose as the baseline.

- Laboratory test results of subjects with clinically significant abnormalities after administration will be listed

6.5.3. Blood Pregnancy Test

Based on SS, the blood pregnancy tests of subjects will be summarized and analyzed by dose group and visit time point, with the latest test result before the first dose as the baseline.

- Visit time points include baseline and D29
- Blood pregnancy test data will be listed

6.5.4. Vital Signs

Based on SS, the clinical significance of vital signs of subjects before and after administration will be summarized by dose group using a shift table (judgment on clinical significance will be made based on the worst result after administration). The vital sign results and changes from baseline will be descriptively analyzed by visit time point, with the latest examination result before the first dose as the baseline.

- Vital sign examination results of subjects with clinically significant abnormalities after administration will be listed

6.5.5. Physical Examination

Based on SS, the clinical significance of physical examination of subjects before and after administration will be summarized by dose group using a shift table (judgment on clinical significance will be made based on the worst result after administration), with the latest examination result before the first dose as the baseline.

- Physical examination results of subjects with clinically significant abnormalities after administration will be listed

6.5.6. 12-lead Electrocardiogram (ECG)

Based on SS, the clinical significance of 12-lead ECG examination of subjects before and after administration will be summarized by dose group using a shift table (judgment on clinical significance will be made based on the worst result after administration). The 12-lead ECG results and changes from baseline will be descriptively analyzed by visit time point, with the latest examination result before the first dose as the baseline.

- 12-lead ECG results of subjects with clinically significant abnormalities after administration will be listed

6.5.7. QTc Analysis

Based on SS, QTc interval of subjects, changes from baseline (ΔQTc), and changes from placebo (ΔΔQTc) will be descriptively analyzed by dose group and visit time point, with the mean value of the results at 3 time points before the first dose as the baseline.

- Visit time points include baseline, 1 h, 1.5 h, 2 h, 3 h, 4 h, 8 h, 12 h and 24 h post-dose on D28
- In case of an explorative study, ΔQTc and drug concentration will be exploratively analyzed using a linear mixed-effects model or Emax model (see the explorative statistical analysis report of the First Bethune Hospital of Jilin University).
- The QTc interval will be classified and analyzed as 480 ≥ QTc > 450, 500 ≥ QTc > 480 and QTc > 500, and the change from baseline in QTc interval will be classified and analyzed as 60 > ΔQTc ≥ 30 and ΔQTc ≥ 60

7. Statistical Analysis Chart Template

See Attachment: BGT-002-004_SAP_mockshell