***This is a guide for an investigator-initiated clinical trial. All components may not be applicable to your study.**

Insert Title of Protocol

The title must be descriptive and concise.

Principal Investigator: Insert full name of investigator and degree(s) leads the study and makes a major contribution

Co-Investigators: List in order of importance to the study

Research Site(s): Insert name of site(s) where research will be conducted

Institution: Insert name of institution the author(s) represent, if applicable

Funding Sponsor: Insert name, address and phone number of funding sponsor, if applicable

NCT Number: If the study requires registration on ClinicalTrials.gov, list the National Clinical Trial (NCT) number assigned at registration

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Background Information

- Name and description of the investigational product(s).
- A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.
- Summary of the known and potential risks and benefits, if any, to human participants.
- Description of and justification for the route of administration, dosage, dosage regimen and treatment period(s).
- A statement that the trial will be conducted in compliance with the protocol, Good Clinical Practice (GCP) and the applicable regulatory requirement(s).
- Description of the population to be studied.
- References to literature and data that are relevant to the trial and that provide background for the trial.

Trial Objectives and Purpose

A clear description of the scientific objectives and the purpose of the trial. Information on estimands, where appropriate, if not included in any other trial-related document, see ICH E9(R1) Addendum on Estimands and Sensitivity Analysis in Clinical Trials to the Guideline on Statistical Principles for Clinical Trials.

Trial Design

The scientific integrity of the trial and the reliability of the results from the trial depend substantially on the trial design. A description of the trial design should include:

- A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.
- A description of the type and design of trial to be conducted (e.g., double-blind, placebo-controlled, parallel design, adaptive design, platform/umbrella/basket, trials with decentralized elements) and a schematic diagram of trial design, procedures and stages.
- A description of the measures taken to minimize/avoid bias, including: (a) Randomization (b) Blinding
- A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s), including a description of the dosage form, packaging and labeling.
- The expected duration of the participant's involvement in the trial and a description of the sequence and duration of all trial periods, including follow-up, if any.
- A description of the "stopping rules" or "discontinuation criteria" and "dose adjustment" or "dose interruption" for individual participants, parts of trial and entire trial.

- Accountability procedures for the investigational product(s), including the placebo(s) and other comparator(s), if any.
- Maintenance of treatment randomization codes and procedures for breaking codes.

Selection of Participants

- Participant inclusion criteria.
- Participant exclusion criteria.
- Mechanism for pre-screening, where appropriate, and screening of participants.

Withdrawal of Consent or Discontinuation of Participation

The investigator may choose to discontinue the participant, or the participant may withdraw their consent. The protocol should specify: (a) when and how to discontinue participants from the trial/investigational product treatment; (b) the type and timing of the data to be collected for withdrawn/discontinued participants, including the process by which the data are handled, in accordance with applicable regulatory requirements; (c) whether and how participants are to be replaced; (d) the follow-up for participants who have discontinued the use of the investigational product.

Treatment and Interventions for Participants

- The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the criteria for dose adjustment(s), the route/mode(s) of administration and the treatment period(s), including the follow-up period(s) for participants for each investigational product treatment/trial treatment group/arm of the trial.
- Medication(s)/treatment(s) permitted (including concomitant and rescue medication) and not permitted before and/or during the trial.
- Strategies to monitor the participant's adherence to treatment.

Assessment of Efficacy

- Specification of the efficacy parameters, where applicable.
- Methods and timing for assessing, recording and analysing of efficacy parameters. Where any trial-related committees (e.g., independent data monitoring committee (IDMC)/adjudication committees) are utilized for the purpose of assessing efficacy data, procedures, timing and activities should be described in the protocol or a separate document.

Assessment of Safety

- Specification of safety parameters.
- The methods, extent and timing for recording and assessing safety parameters. Where any trial-related committees (e.g., IDMC) are utilized for the purpose of assessing safety data, procedures, timing and activities should be described in the protocol or a separate document.
- Procedures for obtaining reports of and for recording and reporting adverse event and intercurrent events; see ICH E9(R1).
- The type and duration of the follow-up of participants after adverse events.

Statistical Considerations

- A description of the statistical methods to be employed, including timing and purpose of any planned interim analysis(ses) and the criteria for the stopping of the trial.
- The number of participants planned to be enrolled and the reason for the choice of sample size, including reflections on or calculations of the power of the trial and clinical justification.
- The level of significance to be used or the threshold for success on the posterior probability in a Bayesian design.
- The criteria for the termination of the trial and the criteria for the stopping of the trial.
- The selection of participants to be included in the planned analyses (e.g., all randomized participants, all dosed participants, all eligible participants, all evaluable participants).
- Procedures for accounting for missing, unused and spurious data.
- Statement that any deviation(s) from the statistical analysis plan will be described and justified in the clinical study report.

Direct Access to Source Records

The sponsor should ensure that it is specified in the protocol or other documented agreement that the investigator(s)/institution(s)/service provider(s) will permit trial-related monitoring, audits, institutional review board/independent ethics committee (IRB/IEC) review and regulatory inspection(s), providing direct access to source records.

Quality Control and Quality Assurance

- Description of identified quality factors and associated risks in the trial unless documented elsewhere.
- Description of the monitoring approaches that are part of the quality control process for the clinical trial.
- Description of the process for the handling of non-compliance with the protocol or GCP.

Ethics

Description of ethical considerations relating to the trial.

Data Handling and Record Keeping

- Specification of data to be collected and the method of its collection. Where necessary, additional details should be contained in a clinical trial-related document.
- The identification of records to be recorded directly into the data acquisition tools (i.e., no prior written or electronic record of data) and considered to be source data.
- A statement that records should be retained in accordance with applicable regulatory requirements.

Financing and Insurance

Financing and insurance, if not addressed in a separate agreement.

Publication Policy

Publication policy, if not addressed in a separate agreement.

References

Identify any literature cited for any information referenced in the protocol. Organize this information like that found in a medical journal.

Attachments

Identify all pertinent documents with the management of this study (e.g. waiver of informed consent, data collection instruments, etc.)