CLINICAL TRIAL PROTOCOL TEMPLATE

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Document History

Version No.	Reason for Amendment	Effective Date
01	**First Edition**	**26 Aug 2024**

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Director, Pharmacovigilance and Clinical Trial Lead Executive Office

Signature:

August 2024

PREFACE

This Clinical Trial Protocol Template was developed using the Ethiopian Clinical Trial Authorisation Guidelines, proclamation 1112/2019, Clinical Trial Regulation No. 964/1923 other legal frameworks as well as international guidelines for the conduction of clinical trial. The template assists investigators and/or sponsors *submitting clinical trial applications to the Ethiopian Food and Drug Authority (EFDA) for authorization and is suitable for all phases of a clinical trial in all therapeutic areas.* However, it is specifically intended for interventional clinical trials on modern medicines and medical procedures as well as traditional medicines to be registered as drugs in Ethiopia.

The EFDA recommends investigators and/or sponsors to use this template to develop clinical trial protocols to be submitted to the Authority for review and authorization. Clinical trial protocols with content and format designed and developed according to this template facilitates the review processes for clinical trial authorization. It is important to note that all sections and subsections should be filled out accordingly. If a section/subsection is not appropriate for the trial, you need to write not-applicable (N/A). The template is available at **www.EFDA.gov.et**.

Amendment (not applicable to new submission)

Affected Section(s)	Summary of Revisions Made	Rationale

Title: *Describe title identifying the study design, population and intervention*

Study ID: *Protocol code number specific for all versions*

Internal Reference Number / Short title: *This should be assigned by the Investigator (not mandatory)*

Ethics Ref: *Insert*

Protocol Version and Date:

Trial registration: *(if not yet registered, name of intended registry*)

Sponsor: *Name and contact information for the trial sponsor*

Principal Investigator: *name, address, telephone number*

Investigators: *Name and title of the investigator(s) who would be) responsible for conducting the clinical trial, and the address and telephone number(s) of the trial site(s)*

Clinical laboratory: *Name(s) and address (es) of the clinical laboratory (ies) and other medical and/or technical department(s) and/or institutions to be involved in the trial (CTA guideline #4.1)*

Protocol signature page

The undersigned Principal Investigator has read and understood the trial protocol detailed above and agrees to conduct the trial in compliance with the protocol.

Principal Investigator (Please print name)	*Signature*	*Site name or ID number*	Date

Following any amendments to the protocol, this page must be updated with the new protocol version number and date and re-signed by the site PI.

KEY TRIAL CONTACTS

Insert full details of the key trial contacts including the following; please add/remove headings as necessary.

Principal Investigator	*Full contact details including phone, email and other applicable communication means*
Sponsor	*Full contact details including phone and email.*
Funder(s)	*Names and contact details of all the organisations providing funding and /or support in kind for this trial.*
Sub-investigators	*Full contact details including phone, email and fax numbers*
Clinical Trials Site	*Full contact details including phone, email and fax numbers (If applicable)*
Statistician	*Full contact details including phone, email and fax numbers*
DSMB Chair	*Name and contact information*

SYNOPSIS

It is useful to include a brief synopsis of the trial for quick reference and/or to use as a stand-alone document. Complete information and, if required, add additional rows.

Trial Title	*Please ensure this is in accordance with the title page*		
Internal ref. no. (or short title)	*Please ensure this is in accordance with the title page*		
Trial registration	*Trial identifier, registry name, registration number and date of registration. If not yet registered, name of intended registry.*		
Sponsor			
Funder	*Names and contact details of all the organisations providing funding and /or support in kind for this trial.*		
Clinical Phase			
Trial Design			
Trial Participants			
Sample Size			
Planned Trial Period	*Include both the total length of the project and the duration of an individual participant's involvement (intervention phase and all follow up including any long term follow up via medical records and registries etc.).*		
Planned Recruitment period	*Indicate start and end dates for recruitment*		
	Objectives	*Outcome Measures*	*Time point*
Primary			
Secondary			
Intervention(s) IMP(s) nIMP(s)	*Provide Formulation, Dose, Route of Administration for each named Investigational Medicinal Product(s)* *Where applicable, provide details of non- Investigational Medicinal Product(s) used in the trial.*		

Other intervention(s)	*If there is an additional investigational intervention such as radiotherapy, surgery or device use provide the relevant details here in addition to the IMP details above.*
Comparator	*Provide Formulation, Dose, Route of Administration for each named comparator*

ABBREVIATIONS

Explain all uncommon or 'technical' acronyms/abbreviations related to the trial. Add or delete line items as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	*Adverse event*
AR	*Adverse reaction*
CRA	*Clinical Research Associate (Monitor)*
CRF	*Case Report Form*
CRO	*Contract Research Organization*
CT	*Clinical Trials*
CTA	*Clinical Trials Authorization*
CTIMP	*Clinical Trial of an Investigational Medicinal Product*
DSMB	*Data Safety Monitoring Board*
DSUR	*Development Safety Update Report*
GCP	*Good Clinical Practice*
IB	*Investigators Brochure*
ICF	*Informed Consent Form*
ICH	*International Conference on Harmonization*
IMP	*Investigational Medicinal Product*
IRB	*Independent Review Board*
PI	*Principal Investigator*
PIL	*Participant/ Patient Information Leaflet*

RA	*Regulatory Authority*
REC	*Research Ethics Committee*
SAE	*Serious Adverse Event*
SAR	*Serious Adverse Reaction*
SMPC	*Summary of Medicinal Product Characteristics*
SOP	*Standard Operating Procedure*
SUSAR	*Suspected Unexpected Serious Adverse Reactions*
TMF	*Trial Master File*

Heading Structure and Flexibility (Delete after referring)

This template uses the typefaces and numbering conventions described in the table below to distinguish between heading levels. To ensure consistency and predictability for all readers, the numbering conventions should be strictly observed. However, fonts, font sizes, and colour are not intended to be fixed requirements, and can be adapted as specific situations may dictate.

Example Heading	**Heading Level**	**Type face in this Template**	**Modification or Deletion**
1	*LEVEL 1(L1)*	*14 point, Times New Roman Bold Black ALLCAPS*	*Do not delete or modify L1or L2 headings Retain heading and Indicate "Not Applicable"*
1.1	*Level 2(L2)*	*14 point Times New Roman Bold Black*	
1.1.1	*Level 3(L3)*	*12 point Times New Roman Bold Black*	*Do not delete or modify Level 3safety subheadings Other Level 3 headings may be deleted or modified as needed*
1.1.1.1	*Level 4(L4)*		
Additional Non-Numbered Heading	*Non-numbered heading*		*Delete heading or modify as needed*

Contents

1. BACKGROUND AND RATIONALE

Include the following adding subheadings if needed:

1.1. Background

- *Name and description of the investigational product(s).*
- *A summary of findings from non-clinical studies that potentially have clinical significance and relevant clinical data from previous studies (phases of trial)*
- *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, 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.*

1.2. Study rationale

State the problem or question (e.g., describe the population, disease, current standard of care, if one exists, and limitations of knowledge or available therapy) and the reason for conducting the clinical trial.

1.3. Risk and benefit

Summary of the known and potential risks (immediate and long-term risk) and benefits, if any, to human participants with a cross reference in details should be described as much as possible.

2. OBJECTIVES AND ENDPOINTS

An objective is the purpose for performing the study in terms of the scientific question to be answered. There must be only one primary objective; the rest will be secondary objectives. Describe the overall, primary and secondary objective(s) of the study in a clear and simple form.

A study endpoint is a specific measurement or observation to assess the effect of the study variable (study intervention). Study endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested.

2.1. **Primary Objective**

Provide a clear, simple statement describing the primary purpose of the study that reflects the main research question.

2.2. **Secondary objective**

Provide a clear, simple statement describing the secondary objectives of the study.

If applicable, it may include exploratory objective (s) that evaluate efficacy or safety of the investigational medicinal product using additional exploratory parameters. (for example, study on biomarkers).

2.3. **Study endpoints**

Primary endpoint

Describe the primary endpoint. Ideally, there should be only one primary endpoint that will enable the primary objective to be met.

Secondary endpoint (s)

Secondary endpoint should match the secondary objectives and be listed in the same order.

If there is explanatory objective (s), the exploratory endpoint(s)should match with the exploratory objective(s) and be listed in the same order.

Insert your objectives, endpoints, and timepoints in the following table. Please ensure these are in accordance with those stated in the synopsis above and on the IRAS form.

Objectives	*Endpoints*	*Timepoint(s) of evaluation of this outcome measure (if applicable)*
Primary Objective		

Example: To compare the effect of treatment A versus treatment B on the levels of a tumor marker (protein X) in the blood		
Secondary Objectives Example: To assess the safety of treatment A in<insert condition/population>		
Exploratory Objectives Please add if applicable, otherwise delete this row		

3. **TRIAL DESIGN**

Briefly summarize the overall trial design (e.g. Randomization, double-blind, placebo-controlled, parallel design, open label, observational), phase of the trial, and framework (e.g., superiority, equivalence, non-inferiority, exploratory) with justification. If controls used, discuss known or potential problems associated with the control group chosen considering the specific disease and intervention(s) being studied.

Provide a description of methods to be used to minimize bias.

Briefly summarize the trial setting (e.g., hospitals, trial centres, homecare, academic centres etc.) indicating number of trial sites and purpose of sites (e.g., recruiting, providing intervention, continuing care etc.).

State the expected duration of participant involvement providing concise details of the number and frequency of visits, including description of the sequence and duration of all trial periods e.g. screening, treatment, and post-treatment follow-up. Include participants 'flowchart throughout the study.

Briefly describe processes for collecting data, and why this method will be used (e.g. type of equipment, checklist, questionnaire, interview schedule, observation schedule).

Include a flowchart for the project as a whole (here, or as an appendix), if appropriate.

4. SELECTION OF STUDY POPULATION

4.1. Trial Participants

Give an overall description of the trial participants.

Example: Participants with <medical condition> of <xyz> severity and <other symptoms/disease specific criteria> and/or healthy volunteers aged <insert age>.

4.2. Inclusion Criteria

Example criteria only (amend as appropriate):

Participant is willing and able to give informed consent for participation in the trial.

Male or Female aged 18 years or above.

Diagnosed with required disease/severity/symptoms, any specific assessment criteria for these, or, if healthy volunteer trial: be in good health. (alter as required) Stable dose of current regular medication (specify type if needed) for at least 4 weeks prior to trial entry. If healthy volunteer trial: have had no course of medication, whether prescribed or over the counter, in the four weeks before first trial dose and no individual doses in the final two weeks other than mild analgesia, vitamins and mineral supplements or, for females, oral contraceptives.

Female participants of childbearing potential and male participants whose partner is of childbearing potential must be willing to ensure that they or their partner use effective contraception during the trial and for at least 3 months for drugs that could have reproductive toxicity profiles thereafter.

Participant has clinically acceptable laboratory and ECG results (specify any other additional assessments) within <insert duration> of enrolment.

In the Investigator's opinion, is able and willing to comply with all trial requirements. Who is willing to allow his or her physician and consultant, if appropriate, to be notified of participation in the trial.

Additional trial specific criteria as required…….

4.3. **Exclusion Criteria**

Example criteria include: Current use of < specify disallowed concomitant medications>, presence of specific devices (e.g., cardiac pacemaker), pregnancy or lactation, Known allergic reactions to components of the<study intervention>, <specify components/allergens>, Febrile illness within <specify time frame>, treatment with another investigational drug or other intervention within <specify time frame>, current substance use within <specify timeframe>, <Specify any condition(s) or diagnosis, both physical or psychological, or physical exam finding that precludes participation>,

4.4. **Additional trial specific criteria as required.**

Note: ensure each criterion is stated as either an inclusion or an exclusion criterion, but not as both.

5. **TRIAL INTERVENTION AND CONCOMITANT THERAPY**

5.1. **Description of Trial Intervention**

Describe the intervention to be administered in each arm of the trial and for each period of the trial including route and mode of administration, dose, and dosage regimen, duration of intervention, packaging, labelling, and storage conditions. Include information for all trial interventions (experimental, placebo, active comparator, sham comparator).

5.2. **Rationale for Trial Intervention**

Provide a rationale or the selection of the dose(s) or dose range, the route of administration, and dosing regimen (including starting dose, dose titration, dose interval) of the trial intervention and any control product. This rationale should include relevant results from previous preclinical studies and clinical trials that support selection of the dose and regimen.

If applicable, justify any differences in specifications, or therapeutic use relative to approved labelling.

5.3. **Dosing and Administration**

Describe the detailed procedures for administration of each participant's dose for trial intervention and control product. Explain specific instructions to trial participants about when or how to prepare and take the dose(s) and how delayed or missed doses should be handled. The protocol should state the conditions under which a dose modification will be made for an individual participant.

- **Treatment of Overdose**

Specify what is meant by trial intervention overdose and any known antidote or therapies.

5.4. **Handling and Storage of Trial Intervention**

Describe storage and handling requirements.

5.5. **Participant Assignment, Randomisation and Blinding**

- **Participant Assignment**

Describe the method of assigning participants to trial intervention.

- **Randomisation**

Describe the randomisation procedures, the method used to generate the randomisation schedule and the source of the randomisation schedule.

- **Blinding and Unblinding**

Describe appropriately blinding and unblinding, criteria for emergency unblinding for the trial should be discussed.

5.6. **Trial Intervention Compliance**

Describe measures employed to ensure and document dosing information and trial intervention compliance (for example, accountability records, diary cards, or concentration measurements). Include a discussion of what documents are mandatory to complete (for example, participant drug log) and what source data/records will be used to document trial intervention compliance.

5.7. **Rescue therapy**

List all medications, treatments, and/or procedures, which may be provided during the trial for rescue therapy and provide relevant instructions about the administration of rescue medications.

6. DISCONTINUATION OF TRIAL INTERVENTION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM TRIAL

Participants may withdraw voluntarily from the study, or the PI may discontinue a participant from the study.

6.1. **Discontinuation of Trial Intervention**

Specify whether participants who discontinue trial intervention can or cannot continue the trial.

Criteria for Permanent Discontinuation of Trial Intervention

Describe the criteria for discontinuation of a participant from trial intervention.

Temporary Discontinuation or Interruption of Trial Intervention

Describe:

- *the criteria for temporary discontinuation or interruption of trial intervention for an individual participant*
- *what to do and which restrictions still apply if the participant needs to temporarily discontinue or interrupt trial intervention*
- *whether they will continue in the trial, and*
- *whether all, or specify which, assessments will be performed for the stated duration of the trial*

6.2. **Re-challenge**

Describe the criteria for re-challenge trial intervention, how to perform re-challenge, number of re-challenges allowed during the trial, and whether all, or specify which, assessments will be performed for the stated duration of the trial.

6.3. **Participant Withdrawal from the Trial**

Participant can voluntarily withdraw from the trial. In such cases, describe whether replacement

is allowed or not.

6.4. **Lost to Follow-Up**

Describe how the trial will define and address participants who are lost to follow-up to help limit the amount and impact of missing data.

6.5. **Trial Stopping Rules**

If applicable, describe any trial-specific stopping rules, including when the trial should be stopped for safety reasons, when a cohort or dose escalation should be terminated, and/or when a given treatment arm should be terminated.

7. TRIAL ASSESSMENTS AND PROCEDURES

Describe the tests and procedures that must be completed at each stage of the study that are pertinent to the specified endpoints.

7.1. Screening/Baseline Assessments and Procedures

Describe any assessments and procedures that are unique to screening/baseline

7.2. Efficacy Assessments and Procedures

Describe efficacy assessments and procedures in this section

7.3. Safety Assessments and Procedures

Describe safety assessments and procedures including guidelines for the management of relevant laboratory or other safety assessment abnormalities

- **Physical Examination**

Provide any specific instructions for the collection and interpretation of physical examinations.

- **Vital Signs**

Provide any specific instructions for the collection and interpretation of vital signs.

- **Electrocardiograms (ECG)**

Provide any specific instructions for the collection, interpretation, and archiving of ECGs

- **Clinical Safety Laboratory Assessments**

Outline any specific instructions for the collection and interpretation of clinical laboratory assessments. • Specify when the use of accredited local laboratories is allowed.

• Specify which laboratory parameters should be included in each panel (for example, for haematology, chemistry, and urinalysis).

- **Suicidal Ideation and Behaviour Risk Monitoring**

Provide suicidal ideation and behaviour risk monitoring by the guidance/guideline in each region, include any specific instructions for the collection and interpretation of the assessment.

7.4. Adverse Events and Serious Adverse Events

- **Definitions of AE and SAE**

Specify the AE and SAE definition]

- **Time Period and/or Frequency for Collecting AE and SAE information.**

Specify the starting and ending time periods for collecting AEs and SAEs.

- **Identifying AEs and SAEs**

Specify how AEs and SAEs will be identified (i.e. spontaneous reporting, solicited questions).

- **Recording of AEs and SAEs**

Identify the Investigator's actions for recording AEs and SAEs, including severity, causality, and the outcome.

- **Follow-up of AEs and SAEs**

Provide the procedures for follow-up of AEs and SAEs until they are resolved or considered stable. Include the assessment tools that will be used to monitor the events and the duration of follow-up after appearance of the events.

- **Reporting of SAEs**

Specify the SAE reporting method (for example, a paper (CRF) to the Sponsor.

- **Regulatory Reporting Requirements for SAEs**

Specify and provide that the Sponsor's legal/regulatory responsibilities to report SAEs to regulatory authorities, ethics committees, and investigators.

Describe the investigators' responsibilities for promptly reporting SAEs to the Sponsor (and to Ethics Committees, where required) to allow the Sponsor to meet their responsibilities.

- **Serious and Unexpected Adverse Reaction Reporting**

Specify SAEs or unexpected adverse reaction, if applicable.

- **Adverse Events of Special Interest**

Specify any Adverse Events of Special Interest (AESI).

- **Disease-related Events or outcomes not qualifying as AEs or SAEs**
  Specify any Disease-Related Events (DREs), disease-related outcomes, or both that will not be reported as AEs or SAEs.

- ***Reporting adverse events to participants***

Describe how study participants are informed about events related to the study procedures.

7.5. **Pregnancy and Postpartum Information (If any)**

- **Participants who become Pregnant during the trial**
  State the study's pregnancy-related policy and procedure, including the assessments to be performed, Type and duration of monitoring, and what information will be collected for a participant who becomes pregnant during the trial.
- **Participants Whose Partners Become Pregnant**

Specify: If the investigator will attempt to collect pregnancy information for a participant's partner, who becomes pregnant while the participant is in the trial. The assessments to be performed, type and duration of monitoring, and what information will be collected

7.6. **Study progress report**

Describe the clinical trial progress report plan including general information, study summary details administrative information, and designation of Investigators.

- **Pharmacokinetics**

Indicate any specific instructions for the collection of samples and interpretation of PK assessments.

- **Genetics**

Describe any specific instructions for the collection of samples for genetic analysis.
• Include the biological samples that will be collected (for example, serum, plasma, etc.) and the retention time for the samples (ensuring alignment with the ICF).
• Indicate the types of analyses that may be studied for each sample.

- **Biomarkers**

Include any specific instructions for the collection of samples and interpretation of biomarkers, including pharmacodynamics.

- **Immunogenicity Assessments (Depending the IP)**

Describe the analytical method to be used for sample analysis.
In case of suspected allergic hypersensitivity, the subject should return to the site and a sample to assess immunogenicity will be collected.

8. **STATISTICAL CONSIDERATIONS**

8.1. **General approach Method used.**

Specify the method used, including descriptive and inferential statistics, normality check, CI, and p-values.

8.2. **Analysis Datasets (Statistical Analysis Plan)**

Indicate analysis sets. Each analysis will be specified here and described in the Statistical analysis Plan.

8.3. **Analyses Supporting Primary endpoint.**

Describing the methods of estimation (analytic approach) in alignment with how the estimations are defined. Sensitivity analyses should be aligned with how the estimands and estimators are defined

8.4. **Statistical Model, Hypothesis, and Method of Analysis**

Describe the statistical model used and the factors that will be included (covariates and interactions) and any rules for handling these factors (for example, pooling of centres).

8.5. **Handling of inter current events of primary estimands**

Provide explanation how data will be handled for the statistical analysis in line with the primary estimands. The handling of inter-current events in statistical analysis should be aligned with the specific estimands strategies being used.

8.6. **Handling of Missing; unused and Spurious data**

The protocol should describe how missing, unused, and spurious data will be handled (for example, type of imputation technique, if any, and provide justification).

8.7. **Sensitivity Analysis**

Outline Sensitivity analyses: are a series of analyses conducted with the intent to explore the robustness of inferences from the main estimator to deviations from its underlying modelling assumptions and limitations in the data.

8.8. **Supplementary Analysis**

Describe any supplementary analysis, if applicable.

8.9. **Analysis Supporting Secondary endpoints.**

In this section, describe the statistical analysis, handling of inter-current events, handling of missing data, and if applicable, sensitivity analysis corresponding to each secondary estimands.

8.10. Safety Analyses

If safety is a primary and/or secondary objective, describe the corresponding safety analyses in the appropriate section.

8.11. Other Analyses

Describe Other Analyses such as Subgroup analyses, adjusted analysis if needed.

8.12. Interim Analysis

Describe any interim analysis and criteria for stopping or adapting the trial.

The description should include, but is not limited to, the following:

- *Any interim analysis plan, even if it is only to be performed at the request of an oversight body.*
- *Describe (briefly and concisely) and reference the applied statistical method.*
- *Who will perform the analysis and when they will be conducted (timing and/or triggers).*
- *The decision criteria—statistical or other—that will be adopted to judge the interim results as part of a guideline for early stopping or other adaptations.*
- *Who will see the outcome data while the trial is ongoing*
- *Whether these individuals will remain blinded to trial groups.*
- *How the integrity of the trial implementation will be protected when any adaptations to the trial are made.*
- *Who has the ultimate authority to stop or modify the trial, (for example, investigator, principal investigator, Data Monitoring Committee, or sponsor).*
- *The stopping guidelines.*
- *If pre-specified interim analyses are to be used for other trial adaptations such as sample size re-estimation, alteration to the proportion of participants allocated to each trial group, and changes to eligibility criteria.*

8.13. Sample Size Determination

Describe number of study participants planned to be enrolled with justification.
Specify if multicentred trial, number of participant enrolled subjects for each trial site

8.14. Protocol Deviations

Describe any plans for detecting, reviewing, and reporting any deviations from the protocol should be described.

8.15. Subgroup analysis

Describe how endpoints will be analysed based on subgroups and why it is not warranted.

9. GENERAL CONSIDERATIONS: REGULATORY, ETHICAL, AND TRIAL OVERSIGHT

9.1. Regulatory and Ethical Considerations

List the prevailing ethical, legal, and regulatory guidelines that will be applied throughout the trial.

List the investigators and sponsor's responsibilities in this regard.

9.2. Relevant Committees including their structure.

Describe the administrative structure of committees that will be reviewing data while the trial is ongoing and the type of committee (for example, Dose Escalation Committee, Data Monitoring Committee or Data Safety Monitoring Board).

9.3. Consenting/Assenting Procedure

- **Consenting procedure including Emergency Consent Process**

Describe consenting/assenting procedures to be followed during the trial

Provide emergency consent process if the trial occurs during an emergency in which the participant or their legally authorized representative is not able or available to give consent.

- Rescreening if needed.

Consent Requirements for Rescreening

9.4. Data Protection

Describe how personal data will be protected and any measures that should be taken in case of a data security breach.

9.5. Early Site Closure or Trial Termination

List the decision rights of sponsor or designee to close a site or terminate the trial. Likewise, list the investigator's right to initiate site closure.

Decision Rights for Site Closure and Trial Termination.

Criteria for Early Closure

Responsibilities following Termination or Suspension

10. RESULTS, OUTCOMES AND FUTURE PLANS

Explain how results will be shared with the medical community, the public and participants. Explain any plans for publication. Describe future use of collected specimens.

11. RISK MANAGEMENT AND QUALITY ASSURANCE

Indicate where Quality Tolerance Limits will be predefined, how they will be monitored during the trial, and expected discussion in the clinical trial report.

Define the responsibilities of the Sponsor with respect to data quality assurance.

12. SOURCE DATA

Define expectations for investigators (for example, maintain source data at the site, ensure availability of current records) and trial monitors (for example, verify CRF data relative to source, safety of participants is being protected, conduct is in accordance with GCP).

Define what constitutes source data and its origin or provide a reference to the location of these definitions.

13. Reference

This is the bibliography section for any information cited in the protocol. Include guidelines on the conduct of research in humans.

- **Annex: Consider all indicated formats on the CTA directive (Directive 964/2023)**

  - ***Ease of accesses: the clinical trial related documents can be obtained through the following means.***

  - ***EFDA web site: - www.EFDA.gov.et***
  - ***e-mail: - clinicaltrial@efda.gov.et***
  - ***Clinical trial web to get any EFDA documents about CT: - http://www.efda.gov.et/doc-category/clinical-trials/***
  - ***Free Tolly: - 8248***