OVERALL SUMMARY/SYNOPSIS – CLINICAL TRIAL PROTOCOL TEMPLATE

*(This template should be filled in and submitted in **Microsoft word format** with bookman old style font size 11 black ink)*

1. GENERAL INFORMATION

Title of Study	
Protocol Identification Number/code	
Protocol Version Number (where applicable)	
Date of Protocol	
TFDA Application Number	
Ethical Clearance Number/ Date of Approval	
Name of Investigational Product or Intervention	
Therapeutic Classification	
Dosage Form(s) and Strength(s)	
Route(s) of Administration	
Name of Comparator Product (where applicable)	
Name and address(es) of the Applicant	
Name and address(es) of the Sponsor	
Name and address(es) of the Principal Investigator (PI)	
Name and address(es) of the Study Monitor	
Name and address(es) of Study Site(s)	
Name and address of the manufacturer of investigational product	
Name and address of the manufacturer of comparator product (if applicable)	
Phase of Trial	
Duration of study	

FOR OFFICIAL USE ONLY:

Assessors Recommendation: ☐ **Recommended** (no outstanding issues) ☐ **Query raised** ☐ **Rejected**	**Comments (if any)**	
Name of 1st Assessor		
Signature of 1st Assessor		**Date assessment**
Name of 2nd Assessor		
Signature of 2nd Assessor		**Date of assessment**

ASSESSOR'S INTRODUCTION / DISCUSSION:

PROPOSED COMMENTS/QUERIES TO BE FORWARDED TO THE APPLICANT:

(Instructions; Please insert the protocol summary in respective sections below the subtitles and delete the guidance notes in blue.)

2. Background and Rationale

(Insert a brief, concise introduction into the clinical problem and previous treatments and developments, i.e., pertinent data from previous preclinical/clinical pharmacology studies and therapeutic exploratory studies taking into account relevant scientific literature (citations by consecutive numbering, with list at end of this section; important or not readily available references may be included with the paper submission, if appropriate). This section should also contain information on the new drug). Provide rationale for conducting the study in Tanzania

Assessor's comments:

3. Objective of the trial

(Insert the objectives that are the same as the objectives contained in the protocol. Include the primary objective and secondary objectives)

Primary Objective(s):

Secondary Objective(s):

Assessor's comments:

4. Endpoints

(Insert the endpoints that are the same as the endpoints contained in the body of the protocol. Include the primary endpoint and important secondary endpoints)

Primary Endpoint(s):

Secondary Endpoint(s):

Assessor's comments:

5. Design

5.1 *Insert summary description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design). Provide a simple summarized snapshot of your study design not to exceed a single page. This section should include a diagram that provides a quick to 1 page. Please present an overview of your study design in a schematic diagram and tables. The data presentation can be adapted depending on the nature of your study and can be customized according to your protocol.*

Example: complete the tables with study-specific information and adapt the table(s) to illustrate your study design.

Arm 1	*Sample size*	*Intervention A*
Arm 2	*Sample size*	*Intervention B*

Include instructions for progressing to next phase (if applicable):

Include a schematic diagram to show the design, procedures and stages including study arms, visits, time-points, interventions etc.

5.2 *Summary of the randomization method and procedures to allocate participants to treatment groups;*

5.3 *Blinding (methods of blinding (masking) and other bias reducing techniques to be used);*

5.4 *Summary description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s), including packaging, and labeling of the investigational product(s);*

5.5 *Maintenance of trial treatment randomization codes and procedures for breaking codes;*

5.6 *Total study duration (anticipated starting/ finishing dates);*

5.7 *Expected duration for each subject including post treatment period etc;*

Assessor's comments:

6. Study participants

6.1 *Provide a brief description of specific characteristics of the trial participants (e.g. disease/ stage/ indication/ conditions/ treatment etc.) as applicable and of diagnostic criteria and assessment*

6.2 *State the Inclusion criteria:*

6.3 *State the Exclusion criteria*

Assessor's comments:

7. Premature Withdrawal / Discontinuation Criteria

7.1 ***Withdrawal criteria:***

7.1.1 *Enumeration of all conditions / criteria and management for drug/ patient's withdrawal or (premature) discontinuation, including voluntary withdrawal by subject without prejudice to future treatment by the physician. The type and timing of the data to be collected for withdrawn participants.*

7.1.2 *State whether and how participants are to be replaced.*

7.1.3 *The follow-up for participants withdrawn from investigational product treatment/trial Treatment*

7.2 *State the stopping rules" or "discontinuation criteria" for individual participants, parts of trial and entire trial;*

8. Drug Formulation

8.1 *(Brief description of the study drug(s) and formulation to be used in the clinical trial. The relationship to the formulations used in the preclinical and/or other clinical trials should be delineated, as applicable. This may also include disclosure of the formulation intended to be marketed and/or any bridging studies which may be necessary, planned, initiated and/or*

already performed if different formulations have been used during clinical development.)

8.2 *Instructions for safe handling;*

8.3 *State the accountability procedures for the investigational product(s), placebos and comparator(s) and disposal;*

Assessor's comments:

9. Dosage Regimen

9.1 *Rationale for dose selection*

9.2 *Provide the following regarding the treatment(s) to be administered:*

- 9.2.1 *The name(s) of all the product(s):*
- 9.2.2 *Dose(s):*
- 9.2.3 *The dosing schedule(s):*
- 9.2.4 *The route/mode(s) of administration:*
- 9.2.5 *The treatment period(s):*
- 9.2.6 *Follow-up period(s) for participants for each investigational product treatment/trial treatment group/arm of the trial:*
- 9.2.7 *Concomitant Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial:*
- 9.2.8 *Procedures for monitoring participant's compliance:*
- 9.2.9 *Wash-out period*

(Description for pre-, during- and post-trial, as applicable)

Assessor's comments:

10. Pre-study Screening and Baseline Evaluation

(Describe in summary the process of clinical validation for participation in the clinical trial, including methodology / schedule of events.)

11. Treatment / Assessment Visits

(Insert the schedule of all events / visits / procedures during the clinical trial)

Assessor's comments:

12. Efficacy Variables and Analysis

12.1 *Description and validation of primary endpoint(s), i.e. responses/changes from baseline over time in relation to clinical trial events. Description and validation of related secondary changes (secondary endpoints) following from clinical trial events.*

12.2 *Provide specification of the efficacy parameters.*

12.3 *Describe the methods and timing for assessing, recording, and analyzing efficacy parameters*

Assessor's comments:

13. Assessment of Safety

13.1 *Specification of safety parameters:*

13.2 *The methods and timing for assessing, recording, and analyzing safety parameters:*

13.3 *Procedures for eliciting reports of and for recording and reporting adverse events and intercurrent illnesses.*

13.4 *The type and duration of the follow-up of subjects after adverse events*

13.5 *RISKS: (Identify potential risks and mitigation strategies (e.g. need for and risks associated with long)*
13.6 *term immunosuppression)*

13.7 *DATA and SAFETY MONITORING PLAN (DSMP):*
(Summarize the Data and Safety Monitoring Plan. Describe measures that will be implemented to minimize risk to study subjects e.g. specific inclusions/exclusions; plans to ensure medical intervention in the case of an adverse event for subjects; plans for surveillance, detection and management of specific adverse events that might or could occur; potential use of an Independent Safety Monitor or Data Safety Monitoring Board (DSMB)

13.8 *Immune Monitoring and immunosuppression: (Describe and justify the plan for immunosuppression and immune monitoring (if applicable)*

Assessor's comments:

14. Assays/methodologies

14.1 *Briefly describe any specialized assays or methodologies that will be used in this clinical study or supporting study/studies (Provide a more detailed summary of assay methods and summarize assay qualification/validation. Indicate where specialized testing will be conducted)*

14.2 *The names and contact addresses of the laboratories to be used for the study;*
14.3 *State the location of the attached draft Material Transfer Agreements (MTAs) in the submission;*
14.4 *State the duration for long term storage of samples and the area to be stored*

Assessor's comments:

15. Statistical analysis plan

15.1 *Specify the planned sample size to be used in the study and its justification*

15.2 *Summary of description of the statistical methodologies to be used to evaluate the effectiveness of the investigational product, including the hypotheses to be tested, the parameters to be estimated, the assumptions to be made and the level of significance and the statistical model to be used.*
15.3 *Analysis of trial parameters (primary/ secondary endpoints), population, demographics, as applicable.*
15.4 *Efficacy analysis methods and results of efficacy end-point analysis.*
15.5 *Safety analysis methods and results of safety end-point analysis.*
15.6 *Exploratory end-point analysis: evaluation effect(s) (or lack of effects) of relevant biochemical/ pharmacological etc parameters, as applicable.*
15.7 *Pharmacokinetic endpoint analysis, as applicable.*

15.8 *Interim analysis and role of Data Safety Monitoring Board, as applicable*
Assessor's comments:
16. Outcome criteria
(Describe criteria that would define whether you would or would not move forward with the subsequent development plan, based upon primary and designated secondary objectives)
17. Data management
(Describe procedures for recording, processing, handling, and retaining raw data and other study documentation)
18. Monitoring plan
(Summary of the monitoring plan) *State the location of the detailed monitoring plan in the submission*
Assessor's comments:
19. Ethical considerations
19.1 *State the ethical clearance reference number and institutions that have approved the trial* *Institution review Board ethical clearance: Number and date* *NIMR ethical clearance number and Date:*
19.2 ***Insurance Details :*** 19.2.1 *Insert local Insurance Company name and address:* 19.2.2 *policy cover number:* 19.2.3 *Validity:* 19.2.4 *Expiry Date:* 19.2.5 *State the location of the Insurance cover in the submission:*
19.3 ***Participant Information sheets and Informed Consent forms:*** *(The contents should be as per ICH guidelines, these guidelines and declaration of Helsinki)* 19.3.1 .*State the version number and dates for both English and Swahili versions* 19.3.2 *State the location of the Participant Information sheets and Informed Consent forms in the submission*
19.4 *State the amount to be reimbursed to the participants*
19.5 *Treatment and/or management of participants and their disease condition(s) after completion of trial*
19.6 *Follow-up of trial study participants after the conclusion of the trial*
19.7 *In case of transfer of materials, provide Material Transfer Agreement (MTA) highlighting among other things, the following:*
19.8 *Identification of the provider and recipient*
19.9 *Identification of the material and the volume of material*
19.10 *Definition of the trial and how the material will and will not be used.*
19.11 *Maintenance of confidentiality of background or supporting data or information, if any*
19.12 *Indemnification and warranties (where applicable)*
19.13 *Details on post-trial access to the products*
Assessor's comments: