Annex 1: CLINICAL TRIAL APPLICATION FORM (CTA)

To be completed by Applicants for all Clinical Trials

Study Title:

Protocol No:

Version No: **Date of protocol:**

Investigational product's name, number or identifying mark:

Comparator product (if applicable):

Concomitant medications (if applicable):

Date(s) of TFDA approval of previous protocol(s):

Sponsor:

Applicant:

Contact Person:
Address:
Telephone Number: **Fax Number:**
Cell phone Number:
E-mail address:

FOR OFFICIAL USE ONLY

Date original application received: **Proposed Clinical Trial Committee meeting date:**

Application/Reference No.:
Application Fee paid:
Signature: **Date:**

(All future communications to TFDA regarding the application should quote the above application/reference number)

Acknowledgement of Receipt of Application (To be completed by TFDA receiving officer). Cover sheet to be sent to the applicant once details above are completed.

Receipt of the application is hereby acknowledged.

Name:……
Signature:……
Date:…… Stamp:

SECTION 1: CHECKLIST AND TABLE OF CONTENTS

(Please check the boxes and indicate pages where each document below is located in the submission file)

1. ☐ Covering letter
2. ☐ Application Form
3. ☐ General investigational plan
4. ☐ Capacity building plans
5. ☐ Overall Summary of the clinical trial Protocol (Hard copy and in MS Word)
6. ☐ Signed and approved protocol
7. ☐ Participant Information Leaflet (PIL), Informed Consent Forms (English and Swahili versions) and any other information to be given to participants.
8. ☐ Declarations by Principal investigator, Co/Sub investigators and Monitor(s)
9. ☐ Joint declaration by Sponsor (or representative) and National Principal Investigator
10. ☐ Certified copy of insurance policy cover of study participants
11. ☐ Ethical clearance certificate/copy of acknowledgement from NIMR (Parallel submission)
12. ☐ Curriculum vitae (CVs) of investigator(s)
13. ☐ Blank Case Report Forms (CRFs)
14. ☐ Serious Adverse Events reporting form to be used in the study
15. ☐ Nonclinical Overall Summary (Hard copy and in MS Word)
16. ☐ Clinical Study Reports
17. ☐ Investigator's Brochure (IB)
18. ☐ Prescribing information sheets
19. ☐ Quality Overall Summary – Chemical Entities (Hard copy and in MS Word)
20. ☐ Certificate of GMP for manufacture of the Investigational products
21. ☐ Certificate of GMP manufacture of the Placebo/Comparator (if applicable)
22. ☐ Trial product Mock up labels and package Insert/s for other trial medicines
23. ☐ Evidence of accreditation/certifications of the designated Laboratories/other evidence of GLP
24. ☐ Letters of Access authorizing TFDA to Drug master Files, Site Reference Files
25. ☐ Full, legible copies of key, peer-reviewed published articles supporting the application
26. ☐ Investigational Medicinal product dossier
27. ☐ Chemistry, manufacturing and quality control data of active ingredient and finished product/dosage form
28. ☐ Pharmacology and toxicology data
29. ☐ Previous human experience data
30. ☐ Prototype product label

For clinical trials involving medical devices and in-vitro diagnostics, item1-17 and the following additional documents should be submitted;

1. ☐Device Description, design and materials including User manual, catalogue of IFU of the device.
2. ☐Marketing history
3. ☐Risk assessment and standard list
4. ☐Toxicology and biological safety
5. ☐Sterilization validation
6. ☐Electrical safety
7. ☐Safety and usefulness of medicinal substance
8. ☐Safety and appropriateness of use of tissues of animal origin
9. ☐Signed and approved protocol with data compiled as prescribed in Annex 3 and current ISO standards.
10. ☐Certificate of ISO/ Quality audit (ISO 13485) for manufacture of the device if applicable.
11. ☐The Investigational product dossier with data compiled in a common submission template (CSDT) as prescribed in TFDA Guidelines for Submission of Documentation for Registration of Medical Devices, Second Edition, 2016 and Guidelines for Submission of Documentation for Registration of In-Vitro Diagnostics, 2016.

NB: incomplete applications will not be processed

SECTION 2: ADMINISTRATIVE AND SUPPLEMENTARY DETAILS

Title of the Study:

Protocol Number/Identification:

Version number

Date of final protocol:

Part 1: CONTACT DETAILS (Name/Address/Tel/Mobile/Fax/E-Mail)

1.1 Applicant:

1.2 Sponsor:

1.3 Local contact person:

1.4 National principal investigator:

1.5 International principal investigator: (if applicable)

1.6 Monitor:

1.7 Study coordinator:

Part 2: DETAILS OF INVESTIGATIONAL PRODUCT(S)

2.1 Name(s) and brief description of Investigational product to be used in trial:

[A summary of the chemistry and manufacturing data, formulation, composition, excipients and strength should be provided. Complete chemistry and manufacturing data should be included in the investigator's brochure. Product(s) registration number(s) and date(s) of registration, if applicable, should be included]

For medical devices and in-vitro diagnostics

(Brand name of the device, common name or preferred name, description of the device as per Global Medical Device Nomenclature (GMDN) or as applicable, GMDN code, category of the device, Model/ series/ system (if applicable) risk class, declaration of conformity (DoC) if applicable, intended use of the device, names and complete address of the manufacturing site(s), market approval status in GHTF member countries and /or other countries)

2.2 Name(s) and brief description (as above) of comparator product(s) and product registration number(s) and date(s) of registration if applicable: [As in 2.1, where applicable. Prescribing information sheet for registered comparator products should be included]

2.3 Name(s) and brief description (as above) of concomitant medication(s) including rescue medications which are required in the protocol, and product registration

number(s) if applicable [As in 2.1, where applicable. Prescribing information sheet for registered products should be included]

2.4 If any of the above products are marketed locally, explain whether locally-sourced products will be used in the trial:

2.5 Details of packaging, storage conditions and shelf-life of IMP:

2.6 Registration status of IMP, for the indication to be tested in this trial, in other countries [i.e. Country: date registered / date applied for / date registration refused / date registration withdrawn by applicant / date registration cancelled by regulatory authority) [Attach as an Annex if necessary]

Part 3: DETAILS OF INVESTIGATORS AND TRIAL SITE(S)

3.1 Details of investigator(s):

[Designation and title of principal investigators/investigators) Include Name/Address/Tel/Mobile/Fax/E-Mail]

3.2 Current work-load of investigator(s):

[Number of studies currently undertaken by investigators as principal and/or co- or sub-investigator, and the total number of patients represented by these studies. Time-commitments of researcher(s) in relation to clinical trial work and non-trial work]

3.3 Details of Trial Site(s):

[Name of site, physical address, contact details, contact person, etc]

3.4 Capacity of Trial Site(s):

[Number of staff, names, qualifications, experience -- including study coordinators, site facilities, emergency facilities, other relevant infrastructure]

Part 4: TRIAL STUDY PARTICIPANTS

4.1 Number of local participants:

4.2 Total number of participants worldwide (where applicable):

4.3 Total enrolment in each local site/centre: [If competitive enrolment, state minimum and maximum number per site.]

4.4 Volunteer base from which local participants will be drawn

4.5 Retrospective data indicating potential of each site to recruit required number of participants within envisaged duration of trial: [Attach as an Annex if necessary]

Part 5: OTHER DETAILS

5.1 Provide an explanation if the trial is to be conducted locally only and not in the host country of the applicant / sponsor:
5.2 Estimated duration of trial:
5.3 Details of other Regulatory Authorities to which applications to conduct this trial have been submitted, but approval has not yet been granted. Include date(s) of application:
5.4 Details of other Regulatory Authorities which have approved this trial. Include date(s) of approval and number of sites per country:
5.5 Details of other Regulatory Authorities or Research Ethics Committees which have rejected this trial, if applicable, and provide reasons for the rejection:
5.6 Details of and reasons for this trial having been suspended at any stage by other Regulatory Authorities, if applicable:
5.7 Previous studies using this agent which have been approved by the Authority:
Approval number:
Title of the study:
Protocol number:
Date of approval:
Principal Investigator:
Date(s) of progress report(s):
Date of final report:

5.8 If any sub-studies are proposed as part of this protocol, indicate whether these will also be conducted locally. If not, please explain:

Part 6: ETHICS

6.1 Ethics Committee responsible for each site, date of approval or date of application:

6.2 Attach copy of response(s) positive or negative made by, and/or conditions required by Ethics Committee(s) if available]

6.3 Details of capacity building component of the trial, if any:

6.4 Details of ICH-GCP training of investigators, monitors, study co-coordinators in terms of conducting this trial:

6.5 Detailed monitoring plan for each site: [Attach as an Annex if necessary]

6.6 Details of trial insurance: [e.g. insurer, policy holder, policy number, insurance cover, period of validity]

6.7 Details of possible conflict of interest of any person(s)/organization(s) who/which will be involved in the trial:

6.8 Remuneration/compensation to be received by investigators, trial participants or others: [Indicate breakdown of costs to be covered, if applicable. Indicate compensation to be received by participants for travel and incidental expenses.]

SECTION 3: DECLARATION BY APPLICANT

Title of the Study:

Protocol No:

Version No: **Date of Protocol:**

Study investigational medicinal product:

I/We, the undersigned has/have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application.

I/We, hereby declare that all information contained in, or referenced by, this application is complete and accurate and is not false or misleading.

I/We, agree to ensure that if the above said clinical trial is approved, it will be conducted according to the submitted protocol and all applicable legal, ethical and regulatory requirements.

Applicant	**Date**
National Principal Investigator	**Date**
National Co-coordinator/Other (State designation)	**Date**