13.2. **Annex 3**. **FORM- PCT-002.03: Clinical trial application form**

EFDA ETHIOPIAN FOOD & DRUG AUTHORITY	**Pharmacovigilance & Clinical Trial Lead Executive Office**	**FORM- PCT-002.03** **SOP/ PCT_CT001**
Title	**Clinical Trial Application Form**	

A. Trial Identification:

Is the application for non-routine clinical trial procedure? Yes ☐

No ☐

If yes, Specify the conditions for non-routine procedures

_____

1. Name of scientific working group ……
   ……..
2. Title of clinical trial (Include trials short title if available)
   ……...
   ……
3. Protocol Number, Date and Version _____
4. Phase of the clinical trial (Phase I, II, III, IV), Bioequivalence, Other specify
   ……
5. State the objective of the trial and the reasons there of……
   ……
6. Duration of (time period for) the trials……

B. Sponsor Identification

1. The name of the sponsor of the trial……
2. Full address of the sponsor……

……

C. Details of investigator (s) State the name(s), telephone number(s) and qualification of the person (s) who will conduct the trial

Name Qualification Address & telephone number……..

Email address……..

D. Details of CRO and/or Clinical trial sites

1. State the name(s), physical address and telephone number of the institution (s) or places where the trial will be conducted. Detail name and address of CRO, Clinical sites, bio analytical site (if required), statistical analysis sites etc. should be provided

……

2. Statement on the capacity of the institutions /trial site to carry out the clinical trial……

……

E. Information on the Investigational product(s), comparator and other concomitantly used medicines/products

1. State the name of the investigational product, its chemical composition, and empirical formulae:

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2. Therapeutic effect of investigation products

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3. Administration route, dosage, dosage interval and duration for investigational product and drug being used asa control……

4. State the name and address of the manufacturing site……

5. Product used as comparator (placebo/other therapy)……...

6. State whether any other medicines/product will be given concomitantly, Yes/No

If yes, please indicate the name of the medicine/product…….

F. Population of the trial participant

1. Description of the participants (e.g. age group of the subjects, type of study participant, sex)

   ……

2. Number of participants expected to take part and Justification there of (based on statistical consideration)

   …….

……..……

G. Ethical committee

1. Is this clinical trial protocol approved by National Research Ethics Review Board(NRERB)? Yes/No

If No, Please provide the reasons thereof…….

……

2. Is this clinical trial protocol approved (has got favourable opinion) by Institutional ReviewBoard (IRB)? Yes/No

If No, Please provide the reasons thereof…….

……

3. If any, Please specify the name and address of other Ethical clearance certificate related to this clinical trial.

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…….

H. Insurance

1. Description of the name and address of the company who will insure all the subjects in the Proposed trial…….

……

2.State the amount of insurance in respect of each participant……..……

I. Regulatory Details:

1. Name other regulatory Authorities of Ethics committees to which this application has been submitted, and/ or approved?_____
2. If Applicable, explain why the Trials is not going to be conducted in the host country of the Applicant/ sponsor? _____
3. If applicable, name other regulatory Authorities or Ethics committees that have rejected this trial and explain the reason. _____
4. If Applicable, provide details and explain why this trial was halted at any stage by other regulatory Authorities.

_____

J.Applicant Identification: who is submitting the Application?

☐ Sponsor ☐ Sponsor's legal representative person/ Organization Authorized by the person to submit the Application

Applicant Name:_____ Address: _____

Signature_____

Name and address of principal investigator

Signature of principal investigator

Name and address of the sponsor

Signature of sponsor

Date…….

Stamps

FOR OFFICIAL USE ONLY

Date of Application Receipt ……

Name of the person who received the application

……

Position……..

Signature ……..