



DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR - 01 Page 1 of 11

Ver. No.: 05

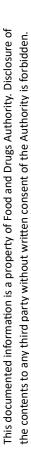
Effective Date: 15/01/2025

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

CHECKLIST FOR SUBMISSION OF CLINICAL TRIALS APPLICATION TO THE FDA

| Applicant's Check | Requirements | % | FDA's Check |
|-------------------|--|-----|----------------|
| | Covering Letter | 20 | |
| | Fees / Proof of payment | 20 | |
| | Clinical Trial Application Form | 4 | |
| | Trial Protocol (including Informed Consent Forms) | 20 | |
| | Investigational Product Information: | 10 | |
| | □ Investigator's Brochure / SmPC | | |
| | □ Report / Summaries of prior clinical trials with the IP | | |
| | ☐ Certificate of GMP manufacture of the trial medicines | | |
| | □ Package Insert/s for other trial medicines | | |
| | ☐ Certificate of GMP manufacture of the placebo /comparator - if appropriate | | |
| | Evidence of accreditation of the designated laboratories | | |
| | Insurance Certificate specific for the trial | 5 | |
| | Signed and completed Declarations by Investigators | 4 | |
| | Ethics Committee's approval of the Protocol | 10 | |
| | Full, legible copies of key, peer-reviewed published articles supporting the application | | |
| | Other appended documents | 4 | |
| | Financial Declaration | 3 | |
| | TOTAL weighted submission | 100 | |

At least 70% of the requirements for a Clinical Trial Application must be available at the time of submission for the application to be accepted for processing.





DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR – 01

Page 2 of 11 Ver. No.: 05

Effective Date: 15/01/2025

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

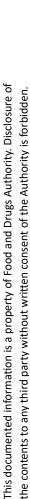
Note:

- i. Summarized review comments on this Clinical Trial Application shall be published on the Clinical Trial Registry on the Authority's website. This is to ensure transparency. However, critical information regarding the trial shall be treated with strict confidentiality.
- Relevant portions of this application form may be photocopied and used if necessary.

1. ADMINISTRATIVE DETAILS

a) Particulars of applicant

| If an individual: |
|--|
| Full name |
| Qualifications |
| Postal Address |
| |
| |
| Telephone number |
| Fax |
| E-mail |
| |
| If an institution: |
| Name of institution |
| Postal Address |
| |
| Telephone Number |
| Fax |
| E-mail |
| Name and status of person in the company making the application on behalf of the |
| company |
| |





b) Sponsor(s) details:

FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR - 01

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

Name..... Postal Address Telephone Number...... Fax..... Fax..... E-mail..... Name of Contact Person(s)..... Postal Address: Telephone Number..... Fax..... E-mail: c) Principal Investigator(s) details: Name of Principal Investigator(s)..... Registration No (If applicable): Postal Address: Telephone Number...... Fax..... E-mail: Name of Principal Investigator(s) Registration No. (If applicable):



DOC. TYPE: FORM

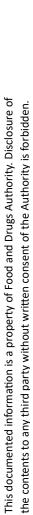
DOC NO.: FDA/CTD/FOR - 01

Ver. No.: 05

Effective Date: 15/01/2025

Page 4 of 11

| Postal Address: |
|----------------------------|
| Telephone Number |
| Fax |
| E-mail: |
| d) Monitor(s) details |
| Independent Monitor's name |
| Postal Address: |
| Telephone Number |
| Fax |
| E-mail: |
| Local Monitor's name |
| Postal Address: |
| |
| Telephone Number |
| FaxE-mail: |





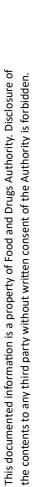
DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR - 01

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

e) Pharmacist(s) details

| Na | me | : |
|-----|------|---|
| Re | gist | ration No: |
| Po | stal | Address: |
| | | |
| | | |
| Те | lepl | none Number |
| Fa | X | |
| E-r | mai | l: |
| | | |
| 2. | TR | IAL DETAILS |
| | a) | Study title and acronym |
| | u, | |
| | | |
| | | |
| | | |
| | b) | Clinical Trial Registration Number i.e. PACTR reference number (including any other additional international trial identifiers if available): |
| | c) | Phase of trial (e.g phase 1): |
| | d) | Proposed date of commencement of trial: |
| | e) | Proposed date of completion of trial: |
| | f) | Name(s) of Trial Centre(s): |
| | 1) | TVallic(3) of Thai Contro(3). |
| | | |
| | | |
| | g) | Location of Trial Centre(s): |
| | | |
| | | |





DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR - 01

Effective Date: 15/01/2025

| | h) Number of participants expected to take part in the study: |
|----|---|
| 2 | |
| 3. | a) Brand Name of Investigational Product: |
| | b) Generic Name of Investigational Product: |
| | c) Dosage Form: |
| | d) Route of Administration: |
| | e) Dosing |
| | |
| | f) Details of control (Name, dosage form, route of administration, dosing etc): |
| | |
| | g) Indicate whether any other drug will be given concomitantly. YES/NO* |
| | If YES, state the name of the drug |
| h) | State the total quantities of all investigational products including products for control group(s) that would be required for the full conduct of the study |
| | |
| | |





j)

FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/CTD/FOR - 01

| i) | | | |
|--|--|----------|----------------|
| St | State any adverse or possible reactions to the product | | |
| | | | |
| | | | |
| | | | |
| k) |) Has the drug been registered in the country of origin? | | YES/NO |
| | If YES a valid certificate of registration in respect of such appropriate authority established for the registration of dru origin shall accompany this application. | • | • |
| | If NO state details | | |
| l) | Have clinical trials been conducted in the country of origin | ? | YES/NO |
| | If YES state details: | | |
| | If NO, give reasons why: | | |
| | | | |
| m) | n) Has the drug been registered for use in Ghana? YE | S/NO | |
| n) |) Has the drug been registered in any other country? YE | S/NO | |
| | If YES state details: | | |
| o) |) Has an application for registration of the drug been made i YES/NO | n any o | ther country? |
| If YES, state details including the date on which the application was lodged | | | |
| | | | |
| p) | Has the registration of the drug been rejected, or refused, in any country? YES/NO | deferred | d or cancelled |





Effective Date: 15/01/2025

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

| If YES, | state d | letails . | | | | | |
|---------|---------|-----------|------|------|------|------|--|
| | | | | | | | |

Current work-load of Investigator(s): Number of studies currently undertaken by trialist(s) as principal and/or co-investigators, and the total number of patients/ represented by these studies. Time-commitments of the researcher(s) in relation to clinical work and non-trial work

Recommended format for response:

| Investigator (Name and designation) | | | | |
|--|---------------------------------|---|---|--|
| Total number of studies being currently undertaken by the investigator | Number | Date of commencement: Expected date of completic of study: | | |
| Total number of patients /participants for which PI is responsible for on specified date | Number | Date | | |
| ESTIMATED TIME PER WEEK | ([168 hours | Hours | % | |
| denominator] | | | | |
| Clinical trials | Clinical work (patient contact) | | | |
| | Administrative work | | | |
| Organization (Practice/University/employer) | Clinical work | | | |
| | Administrative work | | | |
| Teaching | Preparation/evaluation | | | |
| | Lectures/tutorials | | | |
| | | | | |



DOC. TYPE: FORM

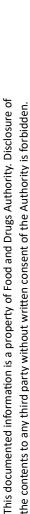
DOC NO.: FDA/CTD/FOR - 01

Ver. No.: 05

Effective Date: 15/01/2025

Page **9** of **11**

| Writing up work for publication/presentation | | |
|---|--|--|
| Reading /sourcing information (e.g., Internet searches) | | |
| Other (specify) | | |





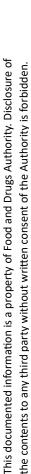
Effective Date: 15/01/2025

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

Declaration and statement of compliance to Good Clinical Practices (GCP)

- 1. I/We the undersigned, hereby declare that all information contained herein is correct and true.
- 2. I/We affirm my/our commitment to upholding the principles of Good Clinical Practice (GCP) in all aspects of our research activities. By submitting this application form, I/We will ensure adherence to the highest standards of ethical conduct, scientific integrity, and participant protection outlined in the GCP principles and local regulatory requirements.

| Sponsor's name/ Authorized Person: |
|------------------------------------|
| Authorized signature: |
| Date: |
| |
| |
| Principal Investigator's name: |
| Authorized signature: |
| Date: |





Effective Date: 15/01/2025

TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

Appendix I: Statement of Compliance to Good Clinical Practice (GCP) by Co-Investigators

I affirm my commitment to upholding the principles of Good Clinical Practice (GCP) in all aspects of the Clinical Trial. By submitting this statement, I will ensure adherence to the highest standards of ethical conduct, scientific integrity, and participant protection outlined in the GCP principles and local regulatory requirements.

| Co-Investigator's name: |
|-------------------------|
| Authorized signature: |
| Date: |

NB: This page should be duly duplicated and signed by all Co-Investigators in the trial. The duplicates should be attached to the application form during submission.