Effective Date: 19th November 2024
Review Date: 18th November 2029

National Agency for Food & Drug Administration & Control (NAFDAC)
Drug Evaluation & Research (DER) Directorate

GUIDELINES FOR CLINICAL TRIALAPPLICATION IN NIGERIA 2024

1. GENERAL

1.1 These guidelines are for the interest of the general public and in particular, individuals and organizations intending to conduct clinical trials in Nigeria.

1.2 It is necessary to emphasize that, no person shall commence a clinical trial or cause a clinical trial to be commenced or conduct a clinical trial, unless the Agency has given a written authorization in relation to the clinical trial.

1.3 It is necessary to emphasize that no person shall import, procure or manufacture a drug product, cosmetic or medical device for the purpose of a clinical test in Nigeria unless he is a holder of a valid Clinical Trial Approval, and the trial is to beconducted in accordance with the terms of the approval and the provisions of any Regulations in force.

1.4 Clinical trial is mandatory for the following:

- 1.4.1 New or relatively new chemical entities, or herbal formulations for which safety/efficacy profile has not been determined.
- 1.4.2 Drugs for new indications.
- 1.4.3 Drugs for new patient population group e.g. Age group and race.
- 1.4.4 New combination drug products.
- 1.4.5 New dosage schedule/regimen.
- 1.4.6 New drug delivery system
- 1.4.7 Medical devices, IVDs and related products to be tested on humans

1.5 These guidelines also apply to Bioavailability/Bioequivalence (BA/BE) for generic medicines.

2. CLINICAL TRIAL APPLICATION

2.1 Applicants should visit the NAFDAC Website (www.nafdac.gov.ng) to access the electronic Clinical Trial Application Platform (eCTAP) to get to the home page of the Application. New applicants should click on REGISTER option to create a profile while returning applicants should simply LOGIN and use their existing log in details to access their application(s).

2.2 The below-listed steps should be followed to make payment for the inspection:

- 2.2.1 Upon acceptance of the Application after Pre-screening on the eCTAP by the Agency, a payment advice is generated and sent to the Applicant or can be collected as a hard copy from Director's Office of the Drug Evaluation & Research Directorate; 1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Express Way Isolo, Lagos.
- 2.2.2 Visit **www.remita.net** to generate a Remita invoice and print out a copy of the invoice.
- 2.2.3 Visit the nearest commercial bank to make the payment and covert the Remita payment to NAFDAC receipt.

2.3 Collect an official receipt of payment from the Finance & Accounts Section; 3rd Floor,

NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

2.4 Submit both electronic/hard copies of the Receipt of payment to the Director, Drug Evaluation & Research Directorate; 1st Floor, NAFDAC Office Complex, Isolo, Lagos

2.5 The application form should be accompanied by the following documents:
- 2.5.1 Evidence of payment for the form.
- 2.5.2 Study Protocol.
- 2.5.3 Informed Consent Form (ICF).
- 2.5.4 Patient Information Leaflet (PIL).
- 2.5.5 Investigator's Brochure (IB
- 2.5.6 Evidence of agreement between the Sponsor and the Investigator.
- 2.5.7 Evidence of Accreditation of Ethics Committee (EC) by the National Health Research Ethics Committee (NHREC).
- 2.5.8 Ethics Committee (EC) Approval from participating centers
- 2.5.9 List of members of the Ethics Committee (EC)
- 2.5.10 Minutes of meeting held to approve the protocol and Informed Consent Form (ICF) Ethics Committee (EC)
- 2.5.11 Evidence to show that the Investigator(s) have undergone basic GCP trainings in the last two years.
- 2.5.12 Curriculum Vitae (CV) of Investigator(s).
- 2.5.13 Sample of all Case Report Forms (CRFs) or Electronic Case Report Forms (e-CRFs) for the study.
- 2.5.14 Evidence of insurance cover for the trial participants.
- 2.5.15 Name and qualification of the trial monitor.
- 2.5.16 List and Charter of the Data Safety Monitoring Board (DSMB).
- 2.5.17 Declaration of Conflict of Interest, Financial Disclosure by the investigator.

2.6 An Authorization shall be issued upon satisfactory review of the submitted application package, otherwise the applicant will be issued a Compliance Directive and expected to respond within 15 workdays of receipt of the Compliance Directive. However, the application clock stops when a Compliance Directive is issued to the applicant (i.e. the date CD is issued) while the clock starts when the applicant submits the response to the CD (date of receipt of submission).

3. PRE-SUBMISSION CONSULTATION MEETING FOR CLINICAL TRIAL APPLICATION (CTA)

3.1 This meeting, which is optional, creates an opportunity for the Sponsor and the Regulator to deliberate on the potential study plan, to address some grey areas, prior to submission of the clinical trial application.

3.2 An application for a pre-submission / consultation meeting for CTA should be made by the sponsor and submitted to the Director; Drug Evaluation and Research Directorate (DER), NAFDAC @ derheadquarters@nafdac.gov.ng (cc: clinicaltrials@nafdac.gov.ng).

- 3.2.1 The application should include proposed date and time for the meeting(Not more

than 2 hours) and a brief synopsis (hard and electronic copies) of the proposed study listing questions (if any) to be addressed by the Directorate, during the meeting.

3.2.2 Confirmation of the date and time of meeting shall be duly conveyed to the applicant.

4. TARIFF

4.1 Academic Trials:

4.1.1 Please to refer to the appropriate section in the NAFDAC Approved Tariff (available at www.nafdac.gov.ng)

4.1.2 All fees attract 7.5% VAT.

4.2 Industry-Sponsored Trials and Bioavailability/Bioequivalence (BA/BE) Studies:

4.2.1 Please to refer to the appropriate section in the NAFDAC Approved Tariff

4.2.2 All fees attract 7.5% VAT.

5. ADDITIONAL PROVISIONS

5.1 The study is to be conducted strictly in accordance with the approved protocol and Regulatory requirements. Any amendment to the protocol shall be subject to the approval of the Agency in line with the Regulatory requirements.

5.2 NAFDAC (the Agency) shall carry out inspection of the approved trial site(s). Please refer to the Good Clinical Practice Guidelines 2020.

5.3 The Agency shall be notified of any Serious Adverse Events (SAEs) within seven calendar days from the date of receipt of the information.

5.4 A progress report shall be submitted to the Agency during the conduct of the trial.

5.5 Final Report of the Clinical Trial shall be submitted to the Agency at the end of the study.

6. CORRESPONDENCE

All correspondence should be addressed to:
The Director-General (NAFDAC)
Attn: The Director,
Drug Evaluation & Research Directorate
1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway Isolo, Lagos State.
NAFDAC website: www.nafdac.gov.ng
E-mail address: der.headquarters@nafdac.gov.ng
Telephone Number: