



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

REGULATORY AND REGISTRATION DIRECTORATE

DOCUMENTATION GUIDELINES FOR CLINICAL TRIAL IN NIGERIA

A. GENERAL

1. Clinical trial is mandatory for the following;
 - New or relatively new chemical entities or herbal formulations for which safety/efficacy profile has not been determined.
 - Drugs for new indications.
 - Drugs for new patient population group e.g. Age group and race.
 - New combination drug products.
 - New dosage schedule/regimen.
 - New drug delivery system
 - Academic clinical trials.

2. 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 be conducted out in accordance with the terms of the approval and the provisions of any Regulations in force.

B. APPLICATIONS

1. Application for Clinical trial shall be submitted to the office of the Director (Registration and Regulatory Affairs), NAFDAC, with the following documents:
 - (a) Research publications on the new chemical entity;
 - (b) Evidence of phase I, II and III studies;
 - (c) Proof of registration in other Countries if imported;
 - (d) Power of attorney (where applicable)
 - (e) Certificate of registration of premises (issued by Pharmacist Council of Nigeria and the annual license to practice of the Superintendent Pharmacist
2. Submission of completed clinical trial form (can be found at www.nafdac.gov) and N5000 + 5% VAT in bank draft made payable to the **National Agency for Food and Drug Administration and Control**.
3. The CTAF should be accompanied with the following documents:
 - (a) Protocol.
 - (b) Informed Consent Form (ICF).
 - (c) Patient Information Leaflet (PIL).
 - (d) Investigator's Brochure.
 - (e) Evidence of agreement between the Sponsor and the Investigator.
 - (f) Evidence of Registration of Institutional Review Boards (IRBs) with the National Health Research Ethics Committee (NHREC).
 - (g) Institutional Review Board's (IRB's) approval from participating centers
 - (h) List of members of the Institutional Review Board.
 - (i) Minutes of meeting held to approve the protocol and Informed Consent Form (ICF).
 - (j) Evidence to show that the Investigator(s) have undergone basic GCP trainings in the last two years.
 - (k) Curriculum Vitae of Investigators.
 - (l) Sample of all Case Report Forms (CRFs) or Electronic Case Report Forms (e-CRFs) for the study.
 - (m) Evidence of insurance cover for the trial participants.

- (n) Name and qualification of the trial monitor.
 - (o) List and Charter of the Data Safety Monitoring Board (DSMB).
4. Authorization to conduct the study is based on satisfactory review and consideration of submitted Protocol and other documents.

At this stage the CT authorization fee (as provided in the Tariff Regulation) must be paid (see table below).

(a) Initiator-Sponsored Trial (Academic Trials)

CLINICAL TRIAL PROPOSED FEES SCHEDULE			
S/N	Type of product	Application fee (=N=)	Approval /Authorization fee (=N=)
i	Imported Drugs	5,000.00	100,000.00
ii	Locally Developed Drugs	5,000.00	100,000.00
iii	Herbal/Natural Medicines (Both Imported and Locally made)	5,000.00	100,000.00

(b) Industry Sponsored Trials (Industrial Trials)

CLINICAL TRIAL PROPOSED FEES SCHEDULE			
S/N	Type of product	Application fee (=N=)	Approval /Authorization fee (=N=)
i	Imported Drugs	5,000.00	750,000.00
ii	Imported Herbal/Natural Medicines	5,000.00	500,000.00
iii	Locally Developed Drugs	5,000.00	250,000.00
iv	Herbal/Natural Medicines (Both Imported and Locally made)	5,000.00	50,000.00

C. THE STUDY

1. The study is to be conducted, strictly in accordance with the approved protocol, NAFDAC-GCP Guidelines and Declaration of Helsinki.
Any change thereof shall be made with the approval of NAFDAC and in line with the Clinical Trial Regulations.
2. NAFDAC GCP inspectors shall visit the approved trial sites for GCP Inspection to ensure that the rights and well being of the subjects/participants are protected during the trial.
(The Inspection also serves to help revalidate the data obtained from the study)

3. The Sponsor shall submit all Serious Adverse Events to the Agency within seven working days from the date of notification.
4. Investigator shall submit progress report of the trial to the Agency quarterly.
5. Final Report of the Clinical Trial shall be submitted for review and comments by Clinical Trial Committee or Experts at the end of the study.
6. A pronouncement is made on the concluded trial; whether adequate or not for marketing authorization.
7. If adequate, the Drug Registration Division is advised (formally) to process the application for registration.

N.B:

- ❖ Authorization to conduct clinical trial does not confer marketing authorization.
- ❖ NAFDAC may withdraw the approval to conduct the trial in the event that the product is being marketed without express approval from the Agency.
- ❖ NAFDAC reserves the right to revoke, suspend, terminate or vary the authorization given to conduct the clinical trial if the terms of authorization are breached.
- ❖ Filing of an application or payment for clinical trial does not confer clinical trial authorization.

For further information visit (www.nafdac.gov.ng)