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

GUIDELINES FOR SUBMISSION OF CLINICAL TRIAL PROGRESS REPORT

1.0 GENERAL

1.1 These guidelines are for the interest of the general public and in particular individuals and organizations intending to submit progress report of ongoing clinical trials in Nigeria.

1.2 It is necessary to emphasize that a quarterly update on the progress of ongoing clinical trials should be submitted to the Agency upon commencement of the clinical trial.

1.3 It is necessary to emphasize that progress reports on ongoing clinical trials in Nigeria should be submitted using the report template in this guideline.

1.4 Clinical trial progress report is mandatory for the following but not limited to:

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 Academic clinical trials.
1.4.8 Bioavailability/Bioequivalence studies on generic medicines

2.0 CLINICAL TRIAL PROGRESS REPORT TEMPLATE

This Clinical Trial Report Template is to be completed in typescript and submitted by the Principal Investigator to the Agency in the following order;

2.1 NAFDAC REFERENCE NUMBER:

2.2 DETAILS OF THE SPONSOR:

Name of Sponsor:	
Address of the Sponsor:	
Contact Person:	
Telephone Number of sponsor:	
E-mail Address:	

2.3 DETAILS OF THE PRINCIPAL INVESTIGATOR (PI):

Name of PI:	
Address of the Site:	
Telephone Number of PI:	

E-mail Address of PI:	

2.4 DETAILS OF STUDY:

Full title of the Study:	
Short title of the Study:	
Protocol Number:	
Name of the Study Product (s):	
Study Objective(s):	
Date of Favorable Ethical Opinion:	
Date of NAFDAC Approval:	
PACTR Number[1]:	
Expected Date of Completion:	

[1] Pan African Clinical Trial Registry

2.5 DETAILS OF COMMENCEMENT AND TERMINATION DATES:

Has the Study Commenced in Nigeria?	Yes/No
If yes, what date?	
If no, state the reasons for the delay in commencement in Nigeria? What is the expected commencement Date?	
Has the study been completed in Nigeria?	Yes/No
If yes, what was the date of completion?	
If no, what is the expected completion date?	
If you do not expect the study to be completed at the expected completion date, give reason(s):	

2.6 SITE(S) INFORMATION:

Number of sites globally:	
Number of Nigerian Sites proposed in original application:	
Number of Nigerian sites approved by	
NAFDAC:	
Number of Nigerian site(s) that have recruited to date:	
Do you plan to increase the total number of Nigerian sites?	Yes/No
Are there changes in the site either within same facility or out of the facility, movement of any equipment etc	

2.7 DETAILS OF PARTICIPANTS' RECRUITMENT:

*Number of participants to be recruited as per protocol:	
*Number of participants recruited:	
Reasons for the disparity (if applicable):	
*Number of participants that completed the study:	
Is the methodology and procedure for recruitment initially approved by the Agency implemented accordingly or there was a deviation, if there is please specify with justification	

Number of participants withdrawn from the study to date due to: i. Withdrawal of consent ii. Loss to follow-up iii. Participants' uncooperative/non-compliant iv. Participant relocation v. Participant worsening condition. vi. Death (where it is not primary outcome), vii. Other (please specify). Total study withdrawals:	
*Number of treatment failures to date (prior to reaching primary outcome) due to: i. Adverse events ii. Lack of efficacy Total treatment failures:	
Details of all protocol non-compliances: i. Sponsor approved: ii. Non-sponsor approved:	
Have there been any serious difficulty in recruiting participants?	Yes/No
If yes, give details:	
Provide details of patient management	
Do you plan to increase the planned recruitment of participants into the study?	Yes/No
Any increase in planned recruitment should be notified to NAFDAC as a substantial amendment for approval.	

*In the case of international trials, please provide separate figures for Nigerian and non-Nigerian participants.

2.8 DETAILS OF SAFETY REPORTS:

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this study in Nigeria?	Yes/No
Have these SUSARs been notified to the Agency within the stipulated Regulatory requirements? *If no, please give reasons for the late notification*:	Yes/No
Have safety report been submitted before?	Yes/No
If yes, please state the reporting time:	
If no, give reasons:	
Are there concomitant treatment or co-morbidities managed so far? If yes, please specify	

2.9 AMENDMENTS:

Have any substantial Protocol amendment. been made during the period under review?	Yes/No
If yes, please give the date and amended protocol number for each. Also give date of approval by NAFDAC.	

2.10 SERIOUS DEVIATION FROM THE APPROVED PROTOCOL OR GOOD CLINICAL PRACTICE (GCP):

Have any serious deviations of the protocol or GCP occurred in relation to this study during this period?	Yes/No
If yes, have you notified NAFDAC?	Yes/No
If yes, please give the date of notification	

2.11 SUMMARY OF ADVERSE EVENTTS (AEs) AND SERIOUS ADVERSE EVENTS (SAEs) ACCOUNTED AT THE SITE (S):

SAE/AE	Causality	Outcome

2.12 SUMMARY OF PROGRESS REPORT TO DATE: Give an overview of the status of the study in view of the information provided above. You may want to add relevant comments on Participants, Study sites, safety issues etc.:

CORRESPONDENCE

All correspondence including Progress Reports should be addressed to:

The Director-General (NAFDAC)
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