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

GUIDELINES FOR CLINICAL TRIAL PROCESS TIMELINES

1. GENERAL

1.1 These guidelines describe the responsibilities and expectations of all the individuals intending to participate in the conduct of clinical trials, thereby providing the guidance on how to comply with the timelines according to NAFDAC Good Clinical Practice

1.2 This guidance document prescribes the minimum time line for Good Clinical Practice (GCP) requirements to ensure quality and safety of the data generated and submitted to NAFDAC.

1.3 These documents also prescribes the minimum timeline necessary for processing of Clinical Trial Applications (CTAs), Processing of Import Permits for Investigational Products, processing of quarterly progress and safety reports, Communicating GCP inspection findings, processing of applications for protocol amendment and processing of final clinical trial reports.

1.4 It is necessary to emphasize that, no regulated product should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of the Food, Drugs and Related Products Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

1.5 These guideline should be followed to comply with timeline in the following areas:

1.5.1 Processing of application and submissions

1.5.2 Serious Adverse Events (SEA) reporting timeline and other timelines

2.0 PROCESSING OF APPLICATIONS AND SUBMISSIONS

ACTIVITY	**TIMELINE******
Processing of Clinical Trial applications (CTAs)	60 days
Processing of import permits for Investigational Products	10 days
Processing of quarterly progress and safety reports	10 days
Notification of receipt of Searsport's	5 days
Communicating GCP Inspection findings	21 days
Processing of applications for protocol amendment	30 days
Processing of final Clinical Trial reports	30 days

Table 1.0

******Timelines specified are working days and excludes process clock stop times**

3.0 SERIOUS ADVERSE EVENTS (SAE) REPORTING TIMELINES

3.1 REPORTS FROM SITES WITHIN NIGERIA

Type of ADR Report	Time Frame For Reporting	Format
Serious Adverse Events	Immediately where possible and in any event, within 72 hours after becoming aware of the information	A Serious Adverse Events form conforming to the CIOMS format (www.cioms.ch) or previously approved by the NAFDAC must be completed and submitted after the site becomes aware of an event. If its Electronic submission, it must comply with ICHE2B (www.ich.org).
• Follow-up reports	Immediately when any of the under listed happens: i. Change in the severity of SAE initially reported. ii. Whenever there is any new development on an initially reported SAE. iii. When the SAE resolves.	Follow-up reports should include an assessment of the importance and implication of any findings. All fatal cases must be followed up with formal autopsy report.
• Frequent adverse events (greater than or equal to	Immediately where possible and in any event, within 7	Line listing (i.e. data for each patient on one line across a report sheet with specific data elements in rows, e.g. sex, age, height etc.)

1% but less than or equal to 10%)	days after becoming aware of the information	
Non Serious Adverse Events	On request and where applicable, submitted as part of an application for registration	Individual reporting in accordance with the data elements specified in the ICH guidance Document E2A (www.ich.org)

Table 1.0

3.2 REPORTS FROM FOREIGN SITES
(For multicenter studies with Nigeria as a participating country)

Serious events	Should be reported immediately where possible and in any event, within 7 days after becoming aware of the information.	Line listing Reports should include an assessment of the importance and implication of any findings.
Foreign regulatory decisions that affect the safety or use of the product	Should be reported within 7 days after any decision.	Detailed report Records with respect to all adverse events in respect of the drug that have occurred inside or outside the country, including information that specifies the indication for use and the dosage form of the drug at the time of the adverse event may be added.

Table 2.0

3.3 OTHER REQUIREMENTS

Literature reports that affect the safety of the product	Should be reported 10 days after becoming aware of the publication.	Detailed report and / or copy of the publication Records with respect to the enrolment of clinical trial subjects including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the drug may endanger the health of the clinical trial subjects or other persons may be added.
Notification of change in nature, severity or frequency of risk factors	Should be reported 14 days after becoming aware of the information	Complete and accurate records with respect to each change made to the Investigator's Brochure, including the rationale for each change and documentation that supports each change
New information impacting on risk benefit profile of product or conduct of trial	Should be reported 7 days after becoming aware of the information.	Communicate with appropriate scientific and medical judgments being applied to each situation. Additional information may include copies of diagnostic test results, laboratory reports or medical record progress notes
Periodic Safety Update Reports (PSUR)	• Submitted on request by The Authority • Submitted within 21 days when it is a condition of registration for a new medicinal product	As a Follow Up Report including copies of diagnostic test results, laboratory reports or medical record progress notes

Table: 3.0

4.0 OTHER TIMELINES

ACTION	REFERENCE	TIMELINE
Notification for the implementation of an urgent amendment necessary to protect the life of subjects	NAFDAC GCP 4.139(a)	Immediate phone call, followed by a written report within forty-eight (48) hours
Quarterly progress reports	NAFDAC GCP 6.2	Within 21 days after the end of the previous quarter. A quarter in this instance is considered as three months beginning from the date of initiation of a specific clinical trial.
Notification of Trial initiation	NAFDAC GCP	NAFDAC should be notified Immediately the trial commences or within ninety (90) days of issuance of the Clinical Trial Authorization letter if the trial does not commence or is delayed.
		Failure of notification within the stipulated time would invalidate the Clinical Trial Authorization issued. A new Authorization would attract administrative fees of 50%.
Notification of interruption of an approved trial before completion in accordance with the protocol.		Within ten (10) working days
Final Report of Clinical Trial as per ICH E3 Guidelines.		Not later than 90 days after the completion of the trial

Table: 4.0

Note: Application process takes a maximum of 60 working days excluding process clock stop times.

CORRESPONDENCE

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