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 Guidelines.

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

1.3 These documents also prescribe the minimum timelines 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 guidelines should be followed to comply with timelines 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 (WORKDAYS)
Processing of Clinical Trial Applications (CTAs)	60
Processing of timeline for CTA during emergency Re-purposed IMP New Chemical Entity	 10 15
Processing of import permits for Investigational Products Issuance - Destruction - Exportation	24 8 7
Processing of quarterly progress and safety reports	20
Processing of response to Compliance Directive (CD)	30

Review of SAE report	21
GCP Inspection report Writing	30
Processing of applications for protocol amendment	30
Processing of final Clinical Trial reports	90

N/B: Timelines specified excludes process clock stop times.
The process clock for each review process starts on the date of commencement of review

3.0 SAFETY REPORTING

3.1 REPORTS FROM SITES WITHIN NIGERIA

Type of ADR Report	Timeframe For Reporting	Format
Fatal or Life threatening Unexpected Serious Adverse Events.	Immediately where possible and in any event, within 7 calendar days, after becoming aware of the information. This is the responsibility of the Principal Investigator. A detailed report (if not available at the initial report) follow up report should be submitted after additional 8 calendar days.	A Serious Adverse Event form conforming to the CIOMS format (www.cioms.ch) or as 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 should include an assessment of the importance and implication of any findings.
Variation/ changes in the reported SAEs.	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.	All fatal cases must be followed up with a formal autopsy report.

Frequent adverse events (greater than or equal to 1% but less than or equal to 10%)	Immediately where possible and in any event, within 7 days after becoming aware of the information	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.)
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)

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

Type of ADR Report	**Timeframe For Reporting**	**Format**
Serious adverse events	Should be reported immediately where possible and in any event, within 15 calendar 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 calendar days after any decision by the sponsor.	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.

3.3 REPORTS FROM SITES WITHIN & OUTSIDE NIGERIA

Type of ADR Report	Timeframe For Reporting	Format
Literature reports that affect the safety of the product	Should be reported 7 calendar 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 7 calendar 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 calendar 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

4.0 OTHER REQUIREMENTS

ACTION	REFERENCE	TIMELINE
Notification for the implementation of an urgent amendment necessary to protect the life of subjects	NAFDAC GCP GUIDELINES 2020	Immediate phone call, followed by a written report within forty- eight (48) hours
Quarterly progress reports	NAFDAC GCP GUIDELINES 2020	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 GUIDELINES 2020	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 charges.
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

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

5.0 REFERENCES

- ***AVAREF Guidelines***
- ***ICH E2A:*** Clinical Safety Data Management; Definitions and Standards for Expedited Reporting.
- ***ICH E2B (R3):*** Clinical Safety Data Management; Data Elements for Transmission of Individual Case Safety Reports.
- ***ICH E3:*** Structure and Content of Clinical Study Reports.
- ***ICH E6 (R1 and R2):*** Guideline for Good Clinical Practice, 2016
- ***ICH E8:*** General Considerations for Clinical Studies

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