FOOD AND DRUGS AUTHORITY

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Technical Advisory Committee on Clinical Trials (TAC-CT)

GUIDELINES ON THE CONTENT AND PROCEDURE FOR DEVELOPMENT AND PUBLICATION OF PUBLIC ASSESSMENT REPORTS FOR CLINICAL TRIAL APPLICATIONS

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Document Revision History

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N/A	01	Initial issue

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1. Introduction

The Food and Drugs Authority's (FDA) goal is to make anonymized clinical information in clinical trial application (CTA) submissions publicly accessible for non-commercial use when the FDA's regulatory review procedure is completed, while complying with Ghana's Data Protection Act, 2012, (Act 843). FDA Public Assessment Reports (FAPARs) are a key assessment output: providing insight and transparency as to the process followed to authorize a clinical trial application submitted to the FDA.

A FAPAR is of great value for regulators and all stakeholders as it summarizes the assessment of the data and information provided by the Sponsor/Applicant. It gives an overview of the non-clinical and clinical information of the trial as well as the quality aspect of the investigational product to be used in the trial.

The essence of the non-clinical narrative is to provide a brief overview of the preclinical data and any relevant preclinical issues identified during assessments. It will be indicated for investigational products (IP) with marketing authorization if the population/dose/dosing regimen/indication/duration has been varied from the originally approved product. The clinical aspect of the report deals with the trial design, objectives, endpoints, and study procedures to be implemented during the conduct of the trial. The quality assessment part of the report is to give a brief on the Good Manufacturing Practice (GMP) compliance status (manufacturing licenses / GMP certificates) of the manufacturer(s) of the IPs (drug substance, drug product, placebo, etc). The general properties including the mechanism of action of the IPs would be captured in the report.

2. Content: Parts of a FAPAR

A FAPAR consists of six (6) parts:

Part 1: Administrative details of the Study

Part 2: Investigational Product(s)

Part 3: Study Summary

Part 4: Scientific discussion (Quality, Safety and Efficacy)

Part 5: Application review process

Part 6: Status after review.

3. Information for development of a FAPAR

The structure and format of the FAPAR for clinical trials authorization has been designed as ***Annex 1***.

In submitting a clinical trial application for FDA evaluation, an applicant must provide the information and/or documents that will be needed – in the event of authorization – for development of the FAPAR.

4. SOPs - Steps in developing a FAPAR

The sequence for developing a FAPAR following authorization of clinical trials application is as follows:

Step 1: The applicant submits documents required for the FAPAR as part of the initial submission to the FDA.

Step 2: FDA compiles the draft FAPAR when the assessment and inspections (when necessary) have been completed successfully.

Step 3: FDA forwards the draft FAPAR to the applicant for review. (Documents are exchanged in electronic format by the applicant and FDA, generally by email).

Step 4: The applicant reviews and comments on (annotates) the draft FAPAR to ensure that the FAPAR does not contain any proprietary or confidential information.

Step 5: The applicant returns the annotated draft FAPAR to FDA.

Step 6: FDA reviews the annotated text – Steps 3 to 6 may need to be repeated if an item requires further clarification – and finalizes the FAPAR.

Step 7: The FDA publishes the FAPAR and informs the applicant accordingly.

Note: In all cases, the applicant shall revert with comments or acceptance within ***20 working days*** of receipt of FDA correspondence. If the FDA does not receive a response within the specified timeframe, the FAPAR shall be deemed acceptable and will be published.

5. Guidance relating to development of contents of FAPAR

The clinical trial application would form the basis for developing the content of the FAPAR for all clinical trials. These documents include:

- Clinical Trials Application Form – for part 1 of a FAPAR
- Investigator's Brochure (IB), Investigational Medicinal Product Dossier (IMPD), Summary of Product Characteristics (SmPC), Product Information Leaflet (PIL) – for part 3 of a FAPAR
- Study Protocol – for parts 2, 3 and 4 of a FAPAR
- Assessment Forms for the specific application – for parts 2, 3 and 4 of a FAPAR
- Guidelines for Clinical Trials Authorization in Ghana – for parts 5 and 6 of a FAPAR

6. Translations

All information related to registered products must be provided in English.

ANNEX 1: Guide on Structure and Format for FDA Clinical Study Public Assessment Report

1. The objective of this guide is to facilitate the compilation of a single core clinical study summary report on evaluations of Clinical Study Applications. It is to ensure transparency while maintaining the confidentiality of proprietary information.
2. This guide applies to clinical trials as defined in Part 8 of the Public Health Act 2012 (Act 851).
3. The guide is intended to assist regulators/officers of the Authority in the development of concise and acceptable summary reports on evaluations of Clinical Study Applications received by the Authority suitable for the public on the Authority's website.
4. The report provides basic administration and technical information on the study and describes evaluators' comments on the application after a detailed assessment.
5. The guidance provided below may be modified as appropriate to capture relevant parts of the study.

PART 1: Administrative Details	
Full Study Title	
Protocol/ Document Number	
Date of Receipt of the Application	
Phase of Study	
Study Registration Details	
Name and Address of Applicant(s)	
Name and Address of Sponsor(s)	
Name and Address of Principal Investigator(s)	
Study Sites	
Study Duration	

PART 2: Investigational Product(s)	
Name of Investigational Product(s) including Comparator(s).	
Justification of Investigational Product(s) including comparators	

PART 3: Study Summary
Study Objectives
Study Design
Indicate where applicable: • *type of allocation of intervention <randomized or not>* • *intervention model <parallel assignment>* • *masking type <open label, blinded (single or double)>* • *primary purpose <prevention, treatment>* • *Study Arms and their corresponding interventions as well as brief procedures <Control (active or placebo) and Experimental>*
Eligibility Criteria
Inclusion criteria list *Exclusion criteria list* *Sex of participants* *Age boundaries*
Date of Commencement (Expected or Actual)
Status of Study
Commenced/Actively recruiting/Enrolment Closed/Analysis/Trial Ended

PART 4: Scientific Discussion
Summary of Review Comments
Quality
What was submitted to support the clinical trial application regarding Quality?
Safety
What was submitted to support the clinical trial application regarding Safety?

PART 4: Scientific Discussion

Efficacy

What was submitted to support the clinical trial application regarding Efficacy?

PART 5: Application Review Process

What was the approval pathway used for the application?

Justification for use of the specific pathway?

Was it reviewed within the specific pathway timelines?

PART 6: Status after Review

When was the application finally approved?

Were there any special conditions issued as part of the approval?