REGULATION OF CLINICAL TRIALS IN GHANA

Scope

This guide covers applications for Clinical Trials as defined under Section 150-166 (Part 8) of the Public Health Act 2012, Act 851.

This document is intended to give guidance to applicants in making applications on Clinical Trials on medicinal products, medical devices or procedures or herbal medicines to the Food and Drugs Authority as the competent Authority for their regulation.

These Guidelines cover the regulatory requirements for authorization of clinical trials in Ghana and are intended to be applied during all clinical stages of drug development prior to and subsequent to product registration. These Guidelines are addressed to investigators, the pharmaceutical industry, Clinical Research Organizations and sponsors of clinical trials, whether for academic purposes or for generation of data, intended for inclusion in the regulatory submissions for medicinal products.

Clinical trials shall be categorized as follows:

1. FDA recommended trials
2. Trials initiated by pharmaceutical companies or agencies
3. Trials initiated by academic and research institutions either locally or as part of an international multi-centre study

Guidance on applications to Ghana Health Service Ethical Review Committee and or Institutional Review Board may be found on their respective websites.

Introduction

These Guidelines seek to ensure that clinical trials conducted in Ghana are designed and conducted according to sound scientific principles and ethical standards within the framework of good clinical practice. Compliance with these Guidelines provides the public with assurance that the rights, safety and wellbeing of trial participants are protected.

Application

Before an application can be submitted to the Authority, the Sponsor must submit proof of registration of the trial with a Clinical Trial Registry. The Authority recommends the Pan African Clinical Trials Registry (PACTR). The applicant may visit the website of PACTR (www.pactr.org), register as a user and follow the instructions on how to register a Clinical Trial. Proof of this registration is to be submitted as part of the CTA during submission to the Authority.

A Clinical Trial may only be conducted in Ghana if:

a) The applicant receives approval from the Ethics Committee(s) responsible for the intuition(s) where the trial is to be conducted.

b) The Authority has issued a final Clinical Trial Authorization certificate

c) The Principal Investigator is resident in Ghana.

Applicant should note that Parallel submission to ethics committee is allowed to reduce any unnecessary delays; however final Clinical Trials Authorization Certificate is issued by the FDA.

Pre-Submission

Pre-submission meetings are also encouraged to discuss pertinent issues prior to formal submissions.

Timelines

Clinical Trial Application process takes maximum of 60 working days. This excludes time taking for applicant to respond to FDA queries. (refer to Appendix 2 of this Guideline).

Additional Information

For additional guidance on making an application for Clinical Trials and on Adverse Reaction reporting, the applicant may consult the FDA's Clinical Trials Application (CTA) Form and the Guidelines for Adverse Reaction Reporting on the website www.fda@fdaghana.gov.gh.

Fees for Clinical Trial Authorization

Category	Rates (US$)	Rates (GH¢)
Industry Funded (Phase I)	15,000.00	
Industry Funded (Phase II)	12,000.00	
Industry Funded (Phase III)	10,000.00	
Investigator/local phases 3 & 4	7,000.00	
Research Institution funded	5,000.00	
Academic Research Trial (Individual)*		2,000.00
Amendment to Clinical Trial protocol	1,000.00	

Links to the Guidelines

- Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Ghana
- Guidelines for Conduct of Clinical Trials in Paediatric Population
- Guidelines for Conduct of Clinical Trials during Emergencies
- Guidelines for Good Clinical Practice in Ghana