

- * Observation of a Technical Advisory Committee meeting on Clinical Trials
- * Evaluation/review of trial reports (SAE reports, quarterly progress reports etc. received from trial sites, safety reports and final clinical study reports)
- * Observation of a Good Clinical Practice inspection at a trial site.

ADMISSION REQUIREMENTS

Applicants must be interested in product development and clinical trials.

OR

Applicants must have been working with a National Regulatory Agency (NRA) for clinical trials for at least one year.

(Applicants with previous experience in clinical trials will have an added advantage)

HOW TO APPLY

Applicants must complete the application form available at <http://www.fdaghana.gov.gh/images/stories/pdfs/Training/RCORE-%20application%20form.pdf>

or pick up a form from the FDA Head Office, Accra.

The application should be supported with the following (with translations where applicable):

- * a copy of participants current curriculum vitae (CV)
- * an introductory letter from the Applicant's institution / agency.
- * a personal statement which should include amongst others the following information:
 - * applicant's motivation to undertake this program (additional information to support this is recommended)
 - * applicant's skills and experience that is relevant to this program
 - * statement on how this program benefit applicant's future career plans

FEES (covers tuition, course materials, in-country transportation, accommodation and refreshments)

- * Foreign applicants: USD 3,500.00
- * Applicants from Ghana : USD 1,500.00

CONTACT US

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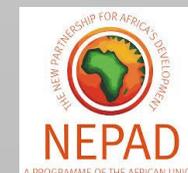
Physical Address/Location

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RCORE CLINICAL TRIAL REGULATORY FELLOWSHIP PROGRAMME

6TH—31ST AUGUST, 2018



ABOUT US

The Food and Drugs Authority (FDA) is an Agency of the Ministry of Health, Ghana and was established in August 1997. It is the National Regulatory Authority mandated by the Public Health Act 2012, (Act 851) to regulate food, drugs (including biologicals, blood and blood products), food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and clinical trials in Ghana.

The FDA, Ghana was designated by the New Partnership for African Development (NEPAD) and the African Regulatory Harmonization (AMRH) as a Regional Centre of Regulatory Excellence (RCORE) in Clinical Trials and Drug Registration in May 2014.

As an RCORE, the FDA in collaboration with the School of Public Health, University of Ghana, seeks to build capacity in Clinical Trials within the sub-region and improve access to medicine through harmonization of regulatory requirements. This will ensure that quality, safe and efficacious medicines are available to African citizens.

DATE OF PROGRAM: 6TH—31ST, AUGUST, 2018

OBJECTIVES OF PROGRAM

* Build capacity and enhance skills of regulators in the area of effective clinical trial regulation through hands-on training and exchange programs to help improve their output.

* Increase regulatory workforce to facilitate quality review of clinical trials conducted in Africa.

* Provide a platform for regulators and researchers to continually share ideas, knowledge and experiences over the years in the aim of improving their activities

* Build capacity and enhance skills of researchers in the area of conduct of clinical trials through hands-on training to help improve their output.

30-DAY INTENSIVE FELLOWSHIP COURSE

COURSE CONTENT

To achieve the above objectives, the FDA has designed an intensive fellowship course covering the following areas;

I. Clinical Trials Authorization

Clinical Trials in Practice

This module investigates the key steps in the logistical and implementation of clinical trials. It clarifies and operationalizes the primary and secondary objectives of clinical trials and implications of design choices for implementation of a trial. The module will also examine the governance, data collection and recruitment methods. Quality assurance and control, data processing and management issues will be explored as well.

Regulatory Issues, Good Clinical & Laboratory Practice

The module seeks to develop participants understanding of the main features relating to regulatory legislation and associated approvals and permissions required to conduct high quality clinical trials. Key issues relating to the legislation of Good Clinical Practice (GCP), understanding GCP, implementing GCP, including risk assessment and trial monitoring will be discussed. Good Laboratory Practice (GLP) in trial settings, Quality control and assurance systems shall also be explored. The focus will be on trials of drug products but trials in variety of other areas and in different locations will be taught.

Ethics of Clinical Research in developing countries

The course aims to discuss the critical ethical issues related to conducting clinical trials in the developing world. The course will cover a historical overview of research ethics in the developing world, medical and human ethics, risk-benefit assessments, vulnerable populations as research subjects, informed consent process and documentation, privacy and confidentiality of research subjects and data, responsible conduct of scientific research, the role and functions of Institutional Review Boards, Data and Safety Monitoring Boards, international research and the Declaration of Helsinki

Protocol Development

The aim of this module is to be able to learn to develop the trial protocol and the steps to be taken for preparing the protocol for a trial: This entails how to develop the data collection forms, understand the required logistical and budgetary issues in the preparation of the protocol, and procedures different funding bodies use to award grants.

II. GCP Inspections

Trial Designs

This module introduces participants to increasing variety of designs used in clinical trials, and this will enable participants to understand their fundamental characteristics and appropriate use in the testing of therapies and other interventions.

Basic Statistics for Clinical Trials

The aim of this unit is to introduce students to basic statistical methods relevant in clinical trials. Students will learn how to select and apply statistical methods to understand data from clinical trials and to present, interpret and discuss the analyses clearly and concisely.

III. Adverse Events and Safety Monitoring (Pharmacovigilance)

Pharmacoepidemiology and Pharmacovigilance

The module provides the history and need for pharmacovigilance. It discusses principles of pharmacovigilance, pharmacovigilance reporting systems, tools for management of reports, global initiatives in pharmacovigilance, regulatory pharmacovigilance, signal detection in pharmacovigilance, post market approval and Phase IV safety Monitoring, safety and data analysis trends, causality assessment principles & analysis.

Reporting and Reviewing Clinical Trials

This course is to enable the students to describe how trials are reported using best practice and how systematic reviews are carried out and reported.

IV. REGULATORY ATTACHMENT

Fellow trainees together with the FDA trainers will follow a 15-day practical regulatory attachment for the trainees at the Food and Drugs Authority's Clinical Trials Department to acquire hands-on training skills on the theoretical aspects of the course.

Hands-on activities will be in the following areas:

* Evaluation of Clinical Trial Applications submitted for regulatory approval which will include protocol and Investigator's Brochure review/assessment, etc.