Clinical Trial Regulatory Fellowship Program

The Medicines Control Authority of Zimbabwe (MCAZ) 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.

The MCAZ in partnership with the Medicines Research Council of Zimbabwe (MRCZ) have designed an intensive course to build capacity and equip regulators in Clinical Trials. The course is designed to promote harmonization in regulatory requirements.

Course Objective:

The objective of this course is to train and equip participants with the requisite knowledge and skills to enable them to evaluate and review clinical trial applications and effectively monitor on going clinical trials. Includes compliance with WHO Global Bench Marking Tools version IV 2018.

Course Format

The course format and delivery has been divided into four modules with each module conducted in 5 days.

Module 1: Drug development and ICH GCP

This module introduces participants to drug development and the importance of clinical trials. The principles of ICH- Good Clinical Practice are introduced here . The module also discusses the Ethics of Clinical trials in developing countries

Module 2: Clinical Trial Protocol development and evaluation :

This module aims to give participants an overview of protocol development, the steps taken in preparing a protocol for a trial. With this background participants will then be introduced to protocol evaluation .

Module 3: GCP inspection and report writing

Participants will have a hands on experience of a GCP inspection and will also learn report writing and grade finding after an inspection.

Module 4: Adverse Events and Safety Monitoring (Pharmacovigilance)

This module aims to provide a background and understanding on Pharmacovigilance , reporting systems, and management tools.

This module will also look at reporting from clinical trial sites and management of reports.

Admission Requirements

1. Applicants must be working with a National Regulatory Agency (NRA) for clinical trials for at least one year..
2. Applicants must be interested in product development or clinical trials.

Application Process

Interested candidates are required to submit an application letter . The application should be supported with:

- A copy of the participants Curriculum Vitae (CV)
- A supporting letter from the NRA or employer

Fees: Foreign applications [Fees to be communicated]

Local applicants: [Fees to be communicated]

Applications to be sent to the Director-General, MCAZ by email mcaz@mcaz.co.zw. Or pvct@mcaz.co.zw

MCAZ also offers on request mentorship/training program especially for participants from regulatory agents that are still building capacity in regulation of clinical trials.

Contact us

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CLINICAL TRIALS

RCORE TRAINING

[DATE TO BE ORGANIZED ON REQUEST]

MCAZ

Protecting your right to quality medicines and medical devices