EDCTP
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MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

AND

KIBONG'OTO INFECTIOUS DISEASES HOSPITAL (KIDH)

SHORT COURSE ANNOUNCEMENT

TITLE: Introduction on Approaches to Clinical Trial Research Designing, Operational Planning, Conducting and Reporting during Drug Development

Introduction

The systematic process before, during and after conduct of clinical trial research (CTR) has made it the strongest source of evidence. Findings from CTR are highly regarded by implementers, policy makers and regulatory authorities all over the world. Henceforth, CTR are the cornerstone of development of interventions (drugs, biological (e.g. vaccine), medical devices, behavioral) used in modern medicine. Unfortunately, Africa has a very limited contribution in CTR despite the fact that it is highly burdened by infectious and currently non-infectious diseases. Among others, inadequate appropriate trainings on CTR are the bottleneck. Therefore, MUHAS and KIDH under the funding support from European and Developing Countries Clinical Trials Partnership (EDCTP) developed this short course training aimed on strengthen CTR competencies (designing, operational planning, conducting and reporting) to clinical researchers aspiring or are currently engaging in CTR. The course capitalizes on practical experience gathered by clinical trial researchers delivering regulatory standard Good Clinical Practice (GCP) compliant CTR in Low- and Middle-Income Countries. Therefore, upon completion trainees will have contextually and settings relevant competences to design, operationalize, conduct and report regulatory standard GCP compliant CTR.

Learning outcomes

At the end of this course the learner is expected to;

1. Describe the CTR designing process with high consideration for participants (or patients) safety
2. Develop CTR protocol (or proposal) in line with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013.
3. Leverage on multidisciplinary team, infrastructures and collaborations to operationalize, conduct and report GCP and Good Clinical Laboratory Practice (GCLP) compliant CTR.
4. Understand governance structure and roles during CTR (particularly funders, sponsor, contract research organization (CRO), sponsor medical experts (SME), clinical research associates (CRA), trial steering committee (TSC), monitors, data safety monitoring committee/board (DSMC/B), principal investigators and delegates).
5. Describe the process of handling investigational products (IPs) to ensure quality, safety and efficacy throughout the

conduct of CTR.

6. Master and use different channels for reporting completed CTR and manuscripts written following Consolidated Standards of Reporting Trials (CONSORT).

Course content

1. Clinical trial research designing
2. Operational planning of clinical trial research
3. Conducting and managing of clinical trial research
4. Clinical trial research reporting

Who should attend?

Medical doctors, nurses, pharmacists, laboratory scientists, epidemiologist/biostatistician, degree in life sciences, chemistry and any other professional degree relevant in drug development, ethical and regulatory authorities.

Mode of instruction

This will be an interactive training utilizing lectures, engaging discussions, videos, small group discussions, case presentation and testimony from experienced clinical trial researchers

Course faculty

This course will be delivered by highly qualified and experienced expertise in CTR from within and outside the country.

Course duration

The Course will be offered for five working days from 6th to 10th May 2024.

Course fee

Fee is not applicable. The training project will cover refreshment (breakfast, lunch and evening tea) and subsistence allowance. The project will not cover accommodation and other extra costs.

Number of course participants

We have limited number of spaces (35 participants allowed)

VENUE: This training will be conducted at MUHAS, SOSMED

Award: Certificates with CPD points will be awarded after attaining a minimum requirement of the course.

Mode of application

Application process should include:

1. One page motivation letter
2. CV (including education qualification, employment & employer's address and work experiences)

The CV and motivation letter should be submitted to rosemagambo66@gmail.com while cc. hamu.mlyuka@muhas.ac.tz and hmlyuka2011@gmail.com.The heading (subject) of email should be: APPLICATION TO CLINICAL TRIAL RESEARCH SHORT COURSE TRAINING

- Successful applicants will be provided with feedback letter within 24 hours since application.
- For further inquiry call/WhatsApp: +255 752 997598 or +255688445680

***NOTE**: Please send your applications before **1st May 2024**. We have limited vacanciestherefore the come first serve first basis will guide the selection process*