EDCTP
European and Developing Countries Clinical Trials Partnership

Consortium For Clinical Research Regulation And Ethics Capacity In The Eastern Africa Region

CCRREEA

Improving Clinical Research Oversight

Introduction

Clinical research in Sub-Saharan Africa (SSA), where high burdens of disease exist, is of particular importance for developing new medicines, advancing our knowledge of disease, improving disease management, as well as product license extensions for existing therapies. As per the clinical trials registries (Pan-African Clinical Trials Registry (PACTR) and ClinicalTrials.gov) there has been a dramatic increase in the number of registered clinical trials over the past decade in the region. National Regulatory Agencies (NRAs) and Institutional Review Boards/ Research Ethics Committees (IRB/RECs) oversee and regulate the conduct of clinical research with the aim of minimizing risk to participants and ensuring respect for the research participant's rights, values and interests (Ezekiel et al. 2000; CIOMS and WHO 2002). The increased number of clinical research taking place in Africa as well as the complexity of clinical research designs require that the local RECs/IRBs, and NRAs have the capacity to efficiently and effectively review the research protocols. This ensures that trials are approved in a timely manner, conducted to the highest ethical standards and in compliance with existing laws and guidelines, hence protection of safety, rights and welfare of the individual participants and research community at large.

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However, conducting research in Eastern Africa region has challenges with respect to; quality of review of clinical research protocols, regulatory burdens imposed by multiple time consuming layers of clinical research approvals, and differing regulatory laws and guidelines as well as lack of clear ethics and regulatory frameworks. Also, inefficiencies relating to administrative matters, the sequential processing of ethics and regulatory approvals and the inflexibilities of regulatory frameworks are equally important factors contributing to the overall problem. Capacity building for the RECs/IRBs, NECs and NRAs is key in addressing such challenges. In addition, promoting changes designed to improve quality of review, timeliness, transparency and predictability of reviews, are all essential elements of good regulatory and good ethical review practices.

Despite effort made in the past years to build coherent frameworks for ethics and clinical research regulation in some of the East African countries, some of the countries in the region are still lagging behind thus hindering conduct of clinical research and efforts of harmonization. With the CCRREEA project, countries with clear ethics and regulatory frameworks will share experiences, build capacity and work with the weak countries in the region to establish and strengthen clinical research regulatory and ethics frameworks in the respective countries.

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Project Objectives

The major objective of the CCRREEA project is to strengthen clinical research regulation and ethics capacity in the Eastern Africa Region with specific aims; (i) Develop and integrate online research information management system for the partner countries, (ii) Strengthen the capacity of the National Regulatory Agencies (NRAs), National Ethics Committees (NECs), Research Ethics Committees (RECs) in the Eastern Africa region towards better quality outputs and improved timelines, (iii) Strengthen the oversight role of NECs and NRAs in clinical research through regional harmonisation initiatives, such as integrating principles, tools and guidelines issued by AVAREF and WHO.

Guiding principles

The CCRREEA project is guided by synergies and networks such as the AVAREF created under the World Health Organization (WHO) that provides an informal capacity-building platform for NRAs and NECs aimed at improving the regulatory oversight of interventional clinical trials being conducted in Africa through strengthening regulatory and ethics reviews, promoting harmonized standards and approaches and accelerating the review of vaccines of high public health value. Our work is further directed by and placed within the framework of an inclusive but decentralised system of ethical review and regulation of clinical research, where RECs/IRBs play an important role. With such a system, RECs/IRBs have a strong institutional base that empowers them to function independently and in a professional and efficient manner. Establishment and or strengthening national REC/IRB accreditation systems to ensure that RECs/IRBs operate and function at acceptable standards. With respect to clinical research involving drugs and biologics, strong drug regulatory regimes are essential to support the work of the NEC and the RECs/IRBs.
We expect that proposed activities in the CCRREEA project will improve the overall efficiency of the review and authorization processes for clinical research in the region, ensure high quality review by RECs/IRBs, NRAs and improve clinical research approval turnaround time not exceeding 60 working days as required by AVAREF-WHO.

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Methods

This project is coordinated by the Uganda National Council for Science and Technology - Uganda and conducted jointly by consortium partners, National Drug Authority- Uganda, Mathari National Teaching and Referral Hospital-Kenya, National Institute for Medical Research and Mihimbili University of Health and Allied Sciences in Tanzania, University of Malawi College of Medicine -Malawi and University of Kigali Rwanda. The countries have networks through the EAHRC and AVAREF that have created joint efforts in capacity building thus will utilise the synergies established to implement the CCRREEA project.

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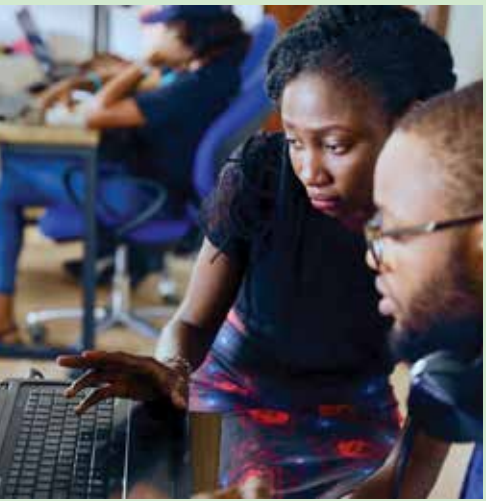

Project Sponsor

CCRREEA project is sponsored by European and Developing Countries Clinical Trials Partnership (EDCTP)

Project Duration

CCRREEA project is to be implemented in a period of 36 months starting January 2021.

Participating Institutions

UGANDA NATIONAL COUNCIL FOR SCIENCE & TECHNOLOGY

Safe Drugs Save Lives

National Institute for Medical Research - Tanzania (NIMR)

Muhimbili University of Health and Allied Sciences (MUHAS) - Tanzania

University of Malawi, College of Medicine (UoM) - Malawi

Mathari National Teaching and Referral Hospital (MNRH) - Kenya

University of Kigali (UoK)- Rwanda

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