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Principal Investigator: Prof Pauline Byakika-Kibwika
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Duration: 36 months
Implementation Sites: Six East African Community Countries (Uganda, Kenya, Tanzania, Burundi, Rwanda and South Sudan)

SCALING UP CAPACITY TO SUPPORT CONDUCT OF CLINICAL TRIALS IN THE EAST AFRICAN COMMUNITY (SCALE-IT)

Background: The East African Community (EAC) has experienced significant increase in volume and complexity of clinical research, driven by epidemics of emerging and remerging infectious diseases such as HIV, Ebola and COVID-19, requiring a robust and pragmatic research regulatory framework.

The overall goal of the SCALE-IT project is to strengthen scientific and ethics capacity in the EAC for high quality research protocol review, and oversight of research conduct, at international standards.

The specific objectives are:

- To train National Research Regulatory Authority (NRRA) personnel, Research Ethics Committee (REC) members, researchers and clinicians on scientific and ethics review, and conduct of research with emerging and complex study designs including adaptive platform trials
- To train NRRA personnel and REC members on oversight and monitoring of clinical trials and
- To train NRRA personnel, REC and research administrators on personal effectiveness and leadership skills (PELS) to manage the increasingly complex research processes.

Methodology: We are implementing this project within a consortium of research scientists from the six EAC partner states collaborating with the EU partner (EPICENTER), with the East African Health Research Commission (EAHRC) as the strong nucleus for coordination and dissemination of results. The project is hosted at the Infectious Diseases Institute (IDI), where, within a previous NIH funded program (5G11 TW011309-01) we developed training curricula for complex and emerging study designs, clinical trial monitoring and PELS, and trained REC members, researchers and REC administrators for 7 RECs in Uganda.

We appointed a Training Advisory Committee (TAC) composed of individuals with expertise in ethics and research. The TAC is composed of at least one member from each partner state. At project initiation, we held a stakeholders' meeting with a sample of members from the EAHRC, NRRAs, RECs, researchers and clinicians in research from each of the six partner states to review and update the training curricula on areas of greatest need and priorities. The results of the stakeholder meeting were presented to the TAC, and utilized to update the three training curricula.

We used best practices learnt by the IDI training team to expand the scope of a blended learning package consisting of classroom teaching and e-learning.

We have established a pool of competent content experts and trainers from the six partner states.

We developed additional interactive e-learning scenarios with challenging ethical case studies for additional study as open access e-learning tools on the IDI Virtual learning environment (VLE).

Participants will undergo two (2) days of classroom face-to-face sessions followed by 4 weeks of online training. During the 2 days face to face training, participants receive orientation and access to the Virtual Learning Environment (VLE). Upon completion of the training, a post test with a pass mark of sixty percent will be completed, and trainees will receive a certificate of attendance.

The e-learning materials remain accessible on the platform for continuous professional development

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Partners and Funders: