East African Consortium for Clinical Research (EACCR2) Terms of References (TORs)

Background

East African Consortium for Clinical Research (EACCR2) is supported by EDCTP2 and coordinated by a secretariat based at the Uganda Virus Research Institute (UVRI), Entebbe, is headed by Dr. Pontiano Kaleebu (UVRI, Uganda) as the overall Project Coordinator and deputized by Prof. Blandina T Mmbaga (KCRI, Tanzania). The EACCR2 had developed from EACCR1 which had its work implemented from May 2009 to April 2012 (Dec2014). The EACCR2 grant will operate from 1st September 2017 to 30th August 2020.

The objectives of EACCR2 network are:

1. To strengthen the collaboration and optimize the use of shared research infrastructures, other capacity building resources and opportunities through all the 5 work packages of this network (i.e. [1] consensus management; [2] multi-centre clinico-epidemiological studies; [3] joint training/mentoring program; [4] shared infrastructure upgrades and utilization and [5] enhanced communication and advocacy).

2. To establish a new node (NID) to manage and establish the needed facilities to conduct clinical trials on neglected, emerging and re-emerging disease that burden the region

3. To boost and deliver an Eastern Africa training and mentorship program (work package 4) promoting an increase and retention of the independent African researcher, research leaders and managers to conduct internationally-competitive clinical trials.

4. To strengthen and strategically expand South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established Eastern Africa institutions in building capacity for conducting high quality clinical research. This will be achieved through all the 5 work packages.

5. To promote networking, and dialogue between researchers, communities and policy makers to maximize the use of health research evidence for shared knowledge management, policy change and improved health programming in Eastern Africa through work package.

The EACCR2 has additional of new developed node –Neglected infectious disease (NID) node and this makes the EACCR2 implementation committee to be composed of four disease specific nodes and one training node. This forms a basis for the implementation committee made of the regionally

coordinating Centre which are;

1. The HIV/AIDS node coordinated by UVRI-Entebbe, Uganda
2. The Malaria node coordinated by KEMRI-Kilifi, Kenya
3. The TB node coordinated by NIMR-Muhimbili, Tanzania
4. Neglected Infectious disease (IEND), Sudan
5. Training node coordinated by KCMC/KCRI, Moshi, Tanzania

EACCR's existing work packages are categorized into: Governance, training, infrastructure, research and networking. Governance is structured regionally into 5 coordinating centers mentioned above.

Steering and project implementation committees will work to support the Network coordination to achieve the planned project objectives.

Terms of References (ToRs)
The TORs present the purpose and scope of the service to be provided, the methods to be used, the standard against which performance is to be assessed or analyses, the resources and time allocated, and the reporting requirements.

The EACCR2 ToRs for the implementation committee will serve as a tool for communication between nodes and secretariat, monitoring project progress across nodes and evaluation. Terms of reference will be an important document linking the nodes, secretariat and the donors

Each node will have its objectives and terms, which will support the implementation of the node, planned activities according to the project agreement. The ToR should provide a clear description of:

1. The rationale for undertaking an assignment, study or task
2. The expected methodology and work plan (activities), including timing and duration and deliverables
3. The anticipated resource requirements, particularly in terms of personnel
4. The reporting requirements

Implementation Committee (IC)

Mandate

- To oversee the management of the project at the EACCR2 secretariat and to supervise the operational activities of the 5 nodes of EACCR2

Functions

1) To supervise the implementation and progress of EACCR2 activities
2) To receive and discuss progress reports from the Node Management Committees
3) To provide annual progress reports to the EACCR2 Steering & Advisory Committee (SAC)

Frequency of meetings

- The Implementation committee meets quarterly to assess project progress
- Usually most meetings are through teleconferences and at least one physical meeting annually.

Composition

1. Overall Project Coordinator (chair), based at Uganda Virus Research Institute (UVRI)
2. Deputy Project Coordinator (Vice Chair), based at Kilimanjaro Clinical Research Institute (KCRI)
3. Training Node Coordinator or designated officer, based at KCRI
4. TB Node Coordinator or designated officer, based at NIMR-Muhimbili
5. Malaria Node Coordinator or designated officer, based at KEMRI-WT
6. NID Node coordinator based at IEND, Sudan
7. HIV Node Coordinator or designated officer, who will also be the technical network liaison officer at the secretariat (UVRI)
8. Project Manager (secretary), based at UVRI
9. Finance Officer at the secretariat
10. Clinical Trial expert-Trudie Lang (member from Oxford University)
11. Head of institution hosting secretariat or administrative designated officer-member (UVRI)
11. Clinical Research expert-Jonathan Kayondo (member)
12. Other co-opted member (whenever necessary) - IT Manager at secretariat

Each node will develop their own project implementation plan and terms of reference to guide the day-to-day implementation including the meeting. The nodes will provide feedback of their meetings to the secretariat/coordinator during the **quarterly Implantation Committee** meeting followed by written progress report which will help the secretariat to combine and monitor the progress across the nodes.

The activities of the implementation committee will be supported by activities/responsibility performed under secretariat level and node level as indicated below;

A. The Sponsor/coordinator responsibility

1. To provide network coordination and management
2. To organize Kick off meeting
3. To lead the network steering committee
4. To monitor node implementation progress
5. To organize and facilitate steering committee meeting
6. To facilitate implementation committee
7. To develop project progress report
8. To organize auditing

Mandate

1. To implement the approved work plans in each of the 5 nodes of the network.

Functions (details included in node-specific terms of references)

1. To operationalize agreed upon main activities in each node of EACCR2
2. To discuss progress of implemented activities in each node and to submit annual reports to the Implementation Committee

Frequency of meeting for Node Management Committees (NMCs)

- Quarterly teleconferences will be held in each node to monitor progress of implemented activities. Physical meetings may be held as side meetings during the Implementation Committee meetings or other convened important EACCR2 meetings in order to minimize costs.
- Composition of NMCs (refer to the node-specific terms of reference)

*Secretaries for each management committee will be selected during each committee's first meeting. The schedule for the subsequent meetings shall be required.B: The node specific responsibilities

Each node will perform its activities implementation according to the project planned activities and deliverable per node specific disease (WP2) and support the achievement of all work packages. The nodes will work with the coordinator in management and implementation of all work packages (WP 1) through a strong network communication and meeting within nodes (WP 5), sharing infrastructure (WP 4) for training and clinical trials (WP 3). Detailed activities of each node will be described under the disease specific node TORs which will also show their work packages and deliverables. Here is a brief summary of some of the planned work under the different nodes:

TB Node: The node will work on writing grants application evaluating a range of Host Directed Therapy as adjuncts using repurposed drugs; support a trial of efficacy, tolerability and adherence to isoniazid preventive therapy; perform first line anti-TB drugs in both new and retreatment TB patients using HPLC and characterize MTB from pre-treatment patients.

HIV Node: The node will conduct feasibility and preparatory studies to get preliminary data for a planned multi-centre feasibility study on HIV pharmaco-vigilance comparing client-based SMS reporting to physician paper-based reporting to improve timely capture of ADRs in 2.5 years; co-fund at least one

ongoing Swedish funded HIV randomized clinical trial on PMTCT, based in Kenya in 2017-2019; facilitate geomapping of the Eastern Africa HIV epidemiological data (e.g. HIV drug resistance profiles, HIV incidence and prevalence, co- and/or super-infections and profiles of adverse drug reactions) to be accessed and used by students and to write and submit at least 2-3 fundable grants for multi-centre HIV randomized trials by Q3 2017-Q1 2018.

Malaria Node: Malaria: Under this node, we propose to: review hospital data in selected hospitals using a predesigned data collection form; carry out multi-site epidemiological studies on malaria prevalence through both longitudinal and cross-sectional; carry out malaria mapping to determine hot spots using GIS systems; initiate clinical trials to test efficacy of ACTs (clinical and parasitological) and determine molecular markers for drug resistance and conduct entomological studies on ecological determinants of mosquito dynamics and insecticide resistance patterns in the region

NID: This node has different diseases with different activities: Dengue: Measure prevalence and transmission of Dengue, and identification of hot spots, Schistosomiasis: Collection of epidemiological data and Development of GIS maps of endemic areas; Leishmaniasis: Evaluation of new diagnostics and GIS mapping of VL and CL endemic areas. Cysticercosis: Evaluation of new detection tools. Hydatidosis: Measurement of prevalence, epidemiology, genotypes and diagnosis and Ebola: Conduct surveillance, develop GIS maps.

Training node: Organize short and long term training, GCL/GCLP, research management and good financial practice and pharmacokinetic courses with a plan to reach at least 260 trainees through conducted 10 disease specific (under disease specific node) and 10 cross-cutting short courses, as outlined in the EACCR2 training inventory which was conducted during project writing phase. The reciprocal monitoring scheme of 20 regional trial monitors will also conduct paired mentoring of new trial monitors. Possible having nested fast-track disease-specific PhD fellowships and postdoctoral fellowships will be conducted.