

EACCR-1: Reciprocal Monitoring Scheme Report

Back ground:

In January 2010, the European and Developing Countries Clinical Trials Partnership (EDCTP) funded the East African Consortium for Clinical Research (EACCR) to initiate a Reciprocal Monitoring Scheme (RMS) in East Africa. This is an innovative practical and affordable scheme for strategic quality management of health research in Africa. The scheme provides mentorship for monitoring the quality and ethics of health research. The scheme provided pragmatic ways of ensuring that trials are conducted in accordance with protocols and established standard operating procedures (SOPs); produced reliable data and accurate results; complied with relevant regulations and safeguarded the rights, safety and wellbeing of participants. It is an accessible regional pool of trained and experienced health professionals who monitor trials using standardized tools in mutual cross-site visits for strategic quality management and exchange of best practices as a planned part-time activity for each monitor. The scheme built on the experience of researchers from the Kenyan Medical Research Institute (KEMRI)/ Wellcome Research Program in Kilifi who have developed an in-house system for monitoring trials. The scheme is a partnership of 13 research and academic institutions in five East African countries (Tanzania, Uganda, Kenya, Sudan, and Ethiopia). The partner institutions nominated members to constitute the 22- member RMS who were trained in 2 monitoring workshops conducted in February 2011 and May 2012 in Kenya (Appendix A, C and D). Eleven experienced monitors were paired with eleven new or less experienced monitors for ‘hands-on’ mentoring in order to increase and sustain capacity. A series of exchange monitoring activities were conducted by the monitors who were allocated in pairs to trials conducted at institutions where they were not employed. A number of trials (vaccine trials, drug safety studies, longitudinal intervention studies) across Africa were monitored by the scheme (see appendix B). In addition, three (3) consultative requests for services from Principal investigators (PI) were conducted at a fee. Activities of the scheme were coordinated by two experienced monitors (one is based at the Uganda Virus Research Institute in Entebbe and the other at Kenyan Medical Research Institute-US Centers for Disease Control Program in Kisumu). They liaise between monitors, research institutes and investigators to ensure that monitoring activities are

conducted as planned. The RMS coordinators were responsible for developing monitoring tools and providing oversight and logistical support. This 'Network of Excellence' was administered by KEMRI/CDC Research & public health collaboration, Kisumu Kenya.

Impact of Reciprocal Monitoring Scheme

1. The cross-site collaboration of partner institutions has contributed to the strengthening of internal Quality Management processes which in turn has led to the improvement of the quality of Clinical Trials in Eastern Africa.
2. The scheme has contributed to the development of practical and cost efficient on-site monitoring among member institutions.
3. It has also contributed to the accelerated search of new or better drugs, vaccines and interventions to control the most targeted infectious diseases in East Africa such as TB, Malaria and HIV.

Challenges encountered

1. Cancellation and reschedule of flights for the monitors leading to change of monitoring visits.
2. Busy schedules for monitors at their primary Jobs resulting into visits that were wide spread.
3. Fixing visit dates that were suitable for both the monitors and the PIs or other relevant study staff.
4. Lack of cooperation from PIs of studies that were selected for monitoring.

Appendix A: List of Monitors (Mentors/Mentees)

First name	Surname	Gender	Nationality	Position held within the network	Institutional Affiliation (site name)
Penina	Soipei	Female	Kenyan	Mentor	Kilifi welcome Trust- Kenya
Johnstone	Thitiri	Male	Kenyan	Mentor	Kilifi Welcome Trust- Kenya
Philip	Nalwande	Male	Ugandan	Mentor	MRC/UVRI Uganda Research Unit on AIDS- Uganda
Zewdu	Hurisa	Male	Ethiopian	Mentee	AHRI- Ethiopia
Sarah	Nanzigu	Female	Ugandan	Mentor	Makerere University – Kampala, Uganda
Beatrice	Mutayoba	Female	Tanzanian	Mentee	NIMRI muhumbili- Tanzania
Jeremiah	Kidola	Male	Tanzanian	Mentee	NIMRI Mwanza -Tanzania
George	Praygod	Male	Tanzanian	Mentee	NIMRI Mwanza- Tanzania
Annet	Nanvubya	Female	Ugandan	Mentor / coordination	UVRI-IAVI HIV Vaccine Program – Uganda – Entebbe, Uganda
Wanze	Kohi	Female	Tanzanian	Mentee	NIMRI Muhumbili- Tanzania
Prossy	Nampija	Female	Ugandan	Mentee	UVRI – Entebbe, Uganda
Muzamil	Mahdi	Male	Sudan	Mentee	Khartoum University-Sudan
Jeniffer	Kigera	Female	Kenyan	Mentor	KAVI Nairobi- Kenya
Elizabeth	Ayuo	Female	Kenyan	Mentor / coordination	KEMRI/ CDC Kisumu- Kenya
Jackline	Nyange	Female	Kenyan	Mentor	KAVI Nairobi- Kenya
Victorine	Owira	Female	Kenyan	Mentor	KEMRI Walter Reed Kisumu- Kenya
Emily	Kemunto	Female	Kenyan	Mentee	KEMRI / CDC Kisumu- Kenya
Vincent	Mutabazi	Male	Rwandese	Mentee	Rwanda Biomedical centre- Rwanda
Miriam	Akello	Female	Ugandan	Mentee	MRC/UVRI Uganda Research Unit on AIDS -Uganda
Stacey	Gondi	Female	Kenyan	Mentor	KEMRI Walter Reed Kisumu- Kenya
Godfather	Kimaru	Male	Tanzanian	Mentee	KCRI Moshi -Tanzania
Margaret	Nakuya	Female	Ugandan	Mentee	Makerere University – Kampala, Uganda
Hyrine	Matheka	Female	Kenyan	Mentor	KEMRI CDC Kisumu- Kenya

Appendix B: Monitoring teams and their allocations

Group/ Team	Monitors	Telephone	Email	Study Assigned and location	PI/Contact person
1.	George K. Godfather	+255 22 2152232 and +255784 607461	fatherdk@yahoo.com	COSTOP study -a randomized controlled trial: MRC/UVRI Uganda	Dr. Paula Munderi: paula.munderi@mrcuganda.org
	Johnstone Thithiri		jthitiri@kilifi.kemri- wellcome.org		
2.	Philip Naluande	+256773399499	Philip.naluande@mrcuganda.org	RTSS – Walter Reed - Kisumu	Dr Walter Otieno wotienol@wrp-ksm.org Stacey and Victorine
	Zewdu Hurisa		hurzew@yahoo.com		
3.	Sarah Nanzigu	+256784843045	snanzigu@yahoo.com	Phase II Randomized, controlled trial-Evaluating the effectiveness of ART Vs primary care Kisumu, Kenya	Dr. Lisa mills: lmills@ke.cdc.gov
	Beatrice Mutayoba	+255757311266	beatricemutayoba@yahoo.com		
	Nakuya Margaret	+256776521799	nakuyamarg@yahoo.com		
4.	Ayuo Elizabeth	+254721317331	EAYuo@ke.cdc.gov	Star Study – Entebbe Uganda	Dr. Noah Kiwanuka
	Jeremiah Kidola	+255754820197	jkidola@yahoo.com		
5.	Mahdi Muzamil	+249912343592	mahdi@iend.org	TB trial-KCRI Moshi Tanzania	Prof. Kibiki H. Semvua
	Johnstone Thitiri		jthitiri@kilifi.kemri- wellcome.org		

6.	Victorine Owira	+254722299 438	vowira@wrp-ksm.org	CTX study – Wellcome Trust – Kilifi, Kenya	Esther Kibaya – Kilifi (four sites) Mombasa, Kilifi, malindi and Nairobi
	Prossy Nampijja	+256392966109	pnampijja@yahoo.com		
	Jackline Nyange	+254722 899 532	jrnyange@kaviuon.org		
7.	Stacey Gondi	+254722430933		Nutritional Support Among African adults Mwanza, Tanzania	John Chagalucha, kidola Jeremiah, Praygod and Godfather
	Nakuya Margaret	+256776521799	nakuyamarg@yahoo.com		
8.	Emily Kemunto Otieno	+254718766156	ekemunto@kemricdc.org	Fetal Heart project Kampala, Uganda	Romano N. Byaruhanga
	Wanze Kohi	+255754233887	wanzejoyce@hotmail.com		
	Miriam Akelo	+256772559404	mirriam_akello@yahoo.com		
9.	Dr. Annet Nanvubya	+256772592717	ananvubya@iavi.or.ug	A phase II open label trial to investigate the effect of Schistosoma mansoni (Sm) infection on the immunogenicity of a candidate TB vaccine, MVA85A, in BCG-vaccinated African adolescents.	Prof. Alison Elliott

10.	Miriam Akelo	+256772559404	mirriam_akello@yahoo.com	An evaluation of the impact of early initiation of HAART on TB treatment outcomes for TB patients co-infected with H.I.V.	Dr. S. Egwaga and Dr. S. Mfinanga
11.	Miriam Akelo	+256772559404	mirriam_akello@yahoo.com	A phase 11, double blind, Randomised, placebo-controlled, multicentre, proof-of concept study of evaluate the safety and Efficacy of AERAS-402 in B.C.G Vaccinated, H.I.V- Uninfected infants without Evidence of Tuberculosis.	Dr. Videlis Nduba and Dr. Grace Kiringa

Appendix C: RMS Monitors- post training in Kilifi-2011



Appendix D: RMS Monitors- post training in Nairobi -2012

