



Professional Development Program for clinical research staff in Siaya, Kenya in preparation for future TB vaccine trials.



Names of authors

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Acknowledgements

KEMRI/CDC Research and Public Health Collaboration

Aeras Global TB Vaccine Foundation

European and Developing Countries Clinical Trials Partnerships

Affiliations

1 KEMRI/CDC Research and Public Health Collaboration

2 Aeras Global TB Vaccine Foundation



Objectives



- Provide a core foundation of knowledge and skills in clinical research.
- Support study teams in achieving research goals.
- Offer support for individual development within the study.
- Support partnerships in similar sites.



Methods



- Train the trainer model to localize and deliver pre-existing modules.
- Exchange visits to partner sites.
- Vienna School of Clinical Research (VSCR) network for clinical research courses.
- Specialized trainings for clinical research teams.
- Pre and post training assessments of learners



Modules Score



Course	Pre-test	Post-test	<i>p-value</i>
CID 1 (n=65) * Clinical Infectious Diseases 1	86	93	>0.05
CID 2 (n=33) * Clinical Infectious Diseases 2	82	89.6	>0.05
E&B 1 (n=60) * Epidemiology & Biostatistics 1	56	84	>0.05
Informed Consent Process (n=45)	81	96	>0.05
GCP (n=9) * Good Clinical Practice	N/A	87	N/A



Exchange Visits



Purpose of visit	Person(s) /Department	#	Destination
Orientation	Prof Dev Program	2	Worcester, SA
Familiarization	Study Coordinators	2	Cape Town, SA
Orientation	Prof Dev Program	2	Jinja, Uganda
Informed Consent Train the Trainer	Prof Dev Program	3	Iganga, Uganda
Supporting Iganga study start up	Adolescent study team	3	Iganga, Uganda
Visit to partner lab	Lab Supervisor	1	Kampala, Uganda



Specialized Trainings



Training	Department	N	Location
HIV counseling and testing	Clinical team	22	Kisumu, Kenya. * KEMRI/CDC Field Station
TST (Mantoux)	Clinical team	9	Kisumu, Kenya. *KNCV/SATVI facilitated
CRRS (reading chest x-rays)	PI & Study Cord. (SC) & Clinicians	7	Cape Town, SA (*SATVI) & Kisumu, Kenya (*SA Trainees).
Conventional lab techniques	Laboratory team	4	Milan, Italy *San Raffaele Lab were hosts
Sputum induction	Clinical team	18	Kisumu, Kenya. * Facilitated by 3 Iganga staff
Visual Basic. Net programming	PI, SC & Data team	6	Nairobi, Kenya. * Facilitated by New Horizons



Scholarships Awarded



- 3 PhD studentships ongoing
- 4 Masters programs in the following areas;
 - Public Health
 - Project Planning and Management
 - Clinical Trials
 - Biomedical Science



VSCR Courses



Course	Dates	N	Mean
Biostatistics	12-14 Jun 08	31	67%
Intro to CR	16-19 Jun 08	31	85%
Basic GCP	20-21 Jun 08	30	84%
Ethical Aspects of CR	13-16 Jul 09	25	96%
GCLP	17-18 Jul 09	25	88%

Abbreviations: GCP – Good Clinical Practice, CR – Clinical Research, GCLP – Good Clinical Laboratory Practice



Discussion & Conclusions



- Embedding staff development within clinical research can contribute towards bridging the gap in Africa's ability to conduct clinical trials.



Future perspectives (1)



- Advanced GCP course: 26-28 October 2009, VSCR facilitating the training.
- GCP TOT Refresher training: 29 – 30 October 2009 facilitated by VSCR.
- Resource center launch in November 2009.
- Prioritize staff positions in the TB epidemiological studies for role based trainings.



Future perspectives (2)



- Standardize GCP course and build GCP training capacity in collaboration with VSCR for future EDCTP funded research.
- Assess trainings and job performance
- Expand model to other clinical studies.
- Applied for additional training grant through EDCTP to expand Prof. Dev. model to the whole field research station and East Africa region.



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