Building Clinical Trials Capacity Through An Integrated Approach

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KEMRI Wellcome Trust Research Programme

- A research programme housed within the Kenya Medical Research Institute
- Over 800 staff – over 100 scientific staff
- Main campus in Kilifi - smaller campus in Nairobi
- Working in most of east & southern African countries, and also the Arabian peninsula
Research Infrastructures

Labs

Field

Clinical

IT
Clinical trials activities

Currently 12 trials running; others at various stage of approval

Vaccines, Treatment regimes, Nutritional rehabilitation, Public health interventions

• RTS,S – malaria vaccine

• Use of cotrimoxazole in preventing death in malnutrition children post-discharge

• Provider and peer support intervention to improve ART adherence among Kenyan men who have sex with Men
An integrated approach to building Clinical Trials Capacity

Developing trials capacity within wider research capacity building programme

⇒ Generate capacity that is sustained beyond and above trials

⇒ Moving African research centres/universities from being primarily trials executors to trials generators
Integrated capacity for research and clinical trials

Clinical trials driven by locally generated tools and questions and vice versa
Method

- Build sustainable local scientific capacity through training, mentorship and career support
- Develop trials capacity through additional training and consolidated trials facility
Recruitment
Supervision
Mentorship
Infrastructure
Multidisciplinarity
Management

ATTRACT
TRAIN
RETAIN

- PhD training
- Master’s training
- Post graduate Diplomas
- Internships
- Attachments
- School leavers scheme
- Post doctoral support
- Collaborative linkages

TOOLS
- Recruitment
- Supervision
- Mentorship
- Infrastructure
- Multidisciplinarity
- Management

Framework
Building local research capacity

2008 - 2013:

PhD training - 25 completed, 40 current
Masters training - 53 completed, 22 current
Diplomas - 149 Staff

2013-2018

• Focus on research leadership development through enhanced postdoctoral support

In the process of recruiting 16 East African postdocs
CONSOLIDATING CLINICAL TRIALS

Clinical Trials Facility

Head of Clinical Trials
Study Coordinators (6)
Medical Officers (7)
Clinical Officers (6)
Nurses (6)
Quality Assurance (1)
Regulatory Officer (1)
Fieldworker (45)
Administrator
Key roles of CTF

- Trials co-ordination
- Ensuring adherence to all regulatory requirements
- Supporting registration of trials
- Development of community engagement
- Development and execution of monitoring plan
- Training and quality control
- Supporting collaborating groups build their trials management systems
Interaction between PIs and other departments through CTF
Specialised training to build clinical trial research capacity

- At least 10 PhDs based directly on or around clinical trials
- 15 clinicians have received MSc training in clinical trials
- GCP & GCLP training run biannually for all PIs, clinicians and lab technicians
- Internal course on research method, and research ethics and communication for all fieldworkers including those involved in trials,
- Continuing Professional Development for trial staff including areas such as project management and quality control