Improving and Maintaining Clinical Research Capacity in Remote Settings: Timely Delivery of Health Tools

Wilfred Mbacham, MS, DS, ScD, FASI, FCAS

Public Health Biotechnologist,
University of Yaounde I, Cameroon
• **Clinical research** is a branch of medical science that determines the safety and effectiveness of
  – Interventions,
  – devices,
  – diagnostic products and
  – treatment regimens intended for human use.

These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.
A Systems Thinking Model for Africa’s Poorest Nations

- Integral approach inclusive of the environmental and Social drivers of disease
- Adequate planning with strategic development objectives in mind
- Training and retention of Human Resource Capacity
- Creation of Technology Platforms
- Strategic alliances with Upper Income Countries
- Strengthening of Research Governance
Scientific Challenges
ID Vaccine R & D

1. Increased antigen diversity
2. Lack of correlates of protection
3. Lack of animal models
4. Lack of comparators (endpoint, assays, trial design)
5. Increasing disease complexity with NCD
34 African Countries - ACTs as First Line Drug At what Cost?

Map of Africa showing different regions with varying numbers of people:
- 188 million
- 387 million
- 036 million
- 040 million
- 651 million
Challenges in the Status of Drugs

- ACTS is reminiscent of the 1960 CQ story
- Evidence of delay in Parasite clearance time
- Pharmacovigilance studies are too few
- Studies on repeated dosing are insufficient
- New alternatives are too few in the pipeline
- Poor clinical mg’t with rise of co-morbid NCDs
AFRICA is a Kaleidoscope

• Diversity of Populations and Genetics
• Diversity of Pathogens and Co-Evolution
• Diversity of Climatic Conditions and Ecosystems (man-made and natural)
  • Diversity of Cultural Practices
  • Diversity of Colonial Pasts
• Diversity of urban, peri-urban & rural sites
Current Trial Sites are not Reflective of the Kaleidoscope
Taking up the Challenges
The Road to Maturity

High Quality Research Studies

Large-Scale Intervention Trials

Drug Licensure Trials

Small-Scale Vaccine Trials

Large-Scale Vaccine Trials
A Must - Synergies

- Used to describe partnerships where the final outcome of a system is greater than the sum of its parts. A dynamic state in which combined action is favored over the sum of individual component actions.

Common Characteristic:
Long term and heavy investments in human, infrastructural and financial resources
Africa Research Centres of Excellence - backed by long term European synergies

• Gambia – Malaria Research Council, UK
• Kenya – Wellcome Trust Res Centres, UK
• Tanzania - Ifakara Centre R&D, TZ Switzerland
• Uganda – Makerere University, Sweden
• Burkina Faso – Centre Muraz, IRSS, Italy, France
• Gabon – HAS, Lambarene, Germany
• Mali – MRTC Bamako, USA
• Mozambique – CISM, Manhiça, Spain
Centres with a Stamp of Excellence

- A long standing relationship of ≥ 10y with the North
- Long term core funding from a western government for 20-50% core costs
- Core staff of PIs with licensure trial experience
- One-site staff training programmes
- Diversification into – AIDS, TB, Rotavirus pneumoniaminingitis diarrhoeal & RTIs
PLATFORM

• TECHNOLOGY,
• CLINICAL APPLICATIONS &
• INNOVATIVE RESEARCH
• EXCHANGES

• LEAP
• HAT
• CCRP
Lessons Learned from last 10 years of Vaccine trials

• Safety and Reactogenicity
• Immunogenicity
• Efficacy Assessment
• Methods are not uniformised with low correlation between \textit{in vitro} and field studies.

• \textit{Schwartz et al, 2012}
Clinical Trial Capacity

• Strict regulatory boards.
• This requires highly trained staff with mastery of SOP and DM
• Facilities such as laboratory equipment,
• In-patient infant beds
• IT infrastructure including internet or satellite connectivity
• Institutional Review Boards
Regulatory Capacity

• New treatments are rushing in
• New tools are needed to assess these
• The need to conduct risk-benefit assessment for at-risk population in endemic countries
• The need to improve their capacity to evaluate and assess new products
Capacity Building Initiative should be Integrative
Currently Over-burdened: Clinical Research Capacity

- Needed 23 licensure sites in Africa by 2012
- These sites are overstretched into other diseases
- Volunteer population is fatigued
- Global financial crunch has induced an attrition in core research funds
- Dwindling human resources capacity
**My Take Home Message**

With good donor enthusiasm, the challenges to meet the needs of health through research can be addressed in new ways. It is up to us to improve and maintain standardized methodologies, and be at the forefront of new science, continually renewing our workforce in clinical research for the timely delivery of health tools, remembering that to stay developed we must always be developing.