



# Strategies for Developing Staff Capacity to Conduct GCP Compliant Clinical Research in Limited Resource Settings

*Peter Wasswa<sup>1</sup>; Patrick Nabongo<sup>1</sup>; Susan Logoose<sup>1</sup>; Daniel Mwanja-Mumpe<sup>1</sup>; Anne Wajja<sup>2</sup>; Philippa Musoke<sup>2,4</sup>; Harriet Mayanja-Kizza<sup>2,3</sup>.*

1. Makerere University Iganga/Mayuge Demographic Surveillance Site, Uganda;
2. Makerere University Infectious Diseases Institute ;
3. Makerere University Department of Medicine;
4. Makerere University Department of Paediatrics

## Acknowledgements

Aeras Global TB Vaccine Foundation and The European and Developing Countries Clinical Trials Partnership (EDCTP) our funders and collaborators



# Introduction



- Conducting clinical research poses many challenges in limited resource settings.
- Shortage of trained and skilled staff
- Lack of qualified/certified trainers and materials
- The Professional Development Program (PDP) is an Aeras-SATVI model developed to address some of these challenges
- The Tuguluka Program implements this model as part of the TB Vaccine Preparation activities in Uganda



# Purpose of Presentation



- To share the experiences and lessons learnt from the Uganda TB Vaccine Preparation Studies in training study staff using the Professional Development Program model.



# Tuguluka Program Objectives



- Provide a core foundation of knowledge and skills in clinical research
- Offer support for individual development
- Support research team through targeted interventions to address study needs
- Attain external recognition of clinical research as a profession in Uganda
- Serve as a model program for other sites



# Methods (1)



- The Tuguluka team comprised of 4 staff identifies and provides training to ~ 70 staff
- Staff trained according to the duties they perform; role-based training
- Section heads/supervisors and Tuguluka identify training needs
- Training needs also identified using a training task force, Tuguluka and QA field assessments



# Methods (2)



- Both knowledge and skill-based training provided
- Follow-up of training done in the field
- Periodic assessment and refresher trainings in place
- Opportunity for self-paced learning through a resource centre





# Results (1)



- Fifty staff have obtained Aeras GCP certificates and 32 staff trained on how to conduct informed consent
- Sixty six staff have trained on at least one of twenty foundational and role-specific courses since April 2008
- Significant improvement (23%) between pre- and post test scores following trainings in 5 courses.



## Results (2)



- Initial assessment in field shows high conformity to what was taught
- Reduction in error rates of documentation recorded by QA and supervisors (17.1%)
- Participant rights such as confidentiality and voluntarism generally respected



# Discussion & Conclusions



- Tuguluka has made significant strides in cost-effectively training staff to conduct GCP-compliant research
- More effort needed in following up on trainings to ensure participants' rights are protected.



# Future perspectives



- Plan to certify trainers
- Enhance online training
- Certifying specific roles in study
- Retrain staff



tuguluka@ya