

Background Africa carries the largest burden of the poverty-related diseases in the world. Most of her populations live in resource-limited settings. These act as catalysts for poverty-related diseases in those populations. There is urgent need for affordable, safe and effective health technologies to reduce the economic burden of those diseases. Clinical research provides an opportunity for access to new and improved health technologies, which have undergone evaluation in clinical trial settings, in compliance with Good Clinical Practice (GCP) and local regulatory requirements. The local Contract Research Organisations offer cost-effective solutions, human resource capacity and experience in poverty-related diseases research, regulatory affairs, culture and politics.

Methods ClinWin provides clinical development services for poverty-related diseases. It has partnered with industry, not-for-profits and academic sponsors to provide a suite of trial and site management, and sponsor oversight services to local clinical research programs. These services include: training, trial monitoring, quality assurance, ethical and regulatory expertise; contract negotiation and trial coordination among others. Leveraging its indigenous knowledge of the clinical trial landscape in the region, it has developed a database of potential and current local investigators capable of conducting registration trials. The lessons learnt in each project are documented and shared with investigator staff at new sites.

Results We conducted 23 monitoring visits at an academic site for a phase Ib HIV vaccine study and malaria phase IV drug trial monitoring visits in Kenya and Tanzania. Academic epidemiological tuberculosis studies were also conducted and we developed partnerships with professional development programs in industry and academia.

Conclusions Africa is the next frontier for clinical research enterprise, and the need for developing local human resource capacity is critical. This will make the region attractive for industry sponsored trials for poverty-related diseases and other indications.

PA-109 **THE ROLE OF LOCAL CONTRACT RESEARCH ORGANISATIONS IN BUILDING GCP-COMPLIANT CLINICAL RESEARCH IN POVERTY-RELATED DISEASES IN AFRICA: A CASE OF CLINWIN RESEARCH SERVICES**

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