Partnership between Contract Research Organization and Investigator sites to optimize Neglected Tropical Diseases Clinical trials efficiency and Quality

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Background

- Africa populations live in areas at risk of acquiring Neglected Tropical Diseases (NTDs), as result poor health infrastructure, unskilled personnel and political instability.
- The pharma industry investment in NTDs research is declining year by year as result of the rising cost of health technologies development and return on investment.
- The policy makers have advocated for affordable, safe and effective health technologies to reduce the burden of NTDs.
- Clinical trials provide an opportunity for the access to new and improved health technologies to populations living in resource poor countries. Clinical trials must comply with international regulatory, safety and quality standards.
- Partnership with Local Contract Research Organizations (LCRO) offer cost efficient and effective solutions, human resource capacity and experience, ethical and regulatory expertise to new and existing investigator sites.

Methods

- We report on LCRO partnership with investigator sites in Kenya. ClinWin Research Services (ClinWin) is LCRO that provides clinical development services and strategic consulting.
- It has partnered with Clinical research investigator sites located in East and West Africa, conducting sponsored and Investigator initiated NTD clinical trials.
- ClinWin provides outsourced clinical research services, including: trials monitoring, GCP/GCLP training, regulatory and ethical support, quality assurance, contracts and budgets among other out-sourced services.

Results

- We have provided ICH GCP training to four sites in East Africa, study and site management for over six sites. This includes investigator initiated, academic and industry sponsored trials. The main tasks performed are: trials monitoring, quality assurance, ethical and regulatory support, contracts negotiations and trials coordination.
- This approach has provided opportunity for those in-experienced sites in clinical trials to develop in house clinical research capacity and build skills for future clinical trials.
- Leveraging on our indigenous knowledge of the clinical trials landscape in the region, we have linked sponsors with potential sites; and delivered the assigned clinical trials on time, quality and cost.

Conclusion

- Efficient and quality clinical trials are not only cost effective but reduces time to registration and deployment of essential health technologies for NTDs.
- Leveraging on LCRO capacity enables the in-experienced investigator sites to participate in NTDs clinical trials, at cost, time and quality. Africa is attractive for industry sponsored trials for NTDs.
- The lessons learned in each project should be documented and shared with investigator staff at current and new sites.