Oferta de trabajo: Clinical Trial Investigator for Mopeia site (Mozambique)

Description:
ISGlobal – Barcelona Institute for Global Health is a research center in international health whose ultimate goal is to help close the gaps in health disparities between and within different regions of the world. For this, we engage in knowledge generation, translation and implementation. ISGlobal is a WHO Collaborative Center for Malaria Control, Elimination and Eradication.

The Manhiça Health Research Centre (CISM), established in 1996 and represented by the Fundação Manhiça, a legal Mozambican entity established in 2008, aims at conducting and promoting health research in national priority health areas to safeguard the health of the most vulnerable populations.

Venue: Mopeia

THE PROJECT
BOHEMIA is a Unitaid funded, **4-year project** that combines evidence generation and stakeholder engagement to create an enabling environment for ivermectin as a first-in-class endectocide for malaria prevention.
This will be achieved by generating evidence
to support a WHO policy recommendation, briefing and engagement of country and regional leaders and civil society in order to forge country ownership and create demand, as well as ensuring supply of quality product by enabling manufacturer engagement as suppliers of quality, high volume/low cost product sufficient for malaria indication.

Evidence generation will consist of two independently powered cluster-randomized clinical trials in Tanzania and Mozambique with analysis of impact on infection incidence, as well as supporting entomological outcomes.

What We Are Looking for:

ISGlobal and **CISM** are looking broadly for an experienced Site-Clinical Trial Investigator for the BOHEMIA clinical trial, to be conducted in Mopeia, Mozambique.
The project will be conducted over a total of four years, with the clinical trial active for 2 sequential years during the peak malaria season. The overall goal is to advance the development of a complementary vector control strategy to reduce malaria transmission.

Essential duties and responsibilities
- Serve as Mopeia site Clinical Trial Investigator for the BOHEMIA clinical trial and conduct all aspects of the clinical trial strictly to ICH-GCP standards
- Be the primary person responsible for the preparation, tracking and submission of relevant documents to all relevant local and national authorities and ethical committees to obtain clinical trial approval in accordance with Sponsor requirements

- Maintain strict confidentiality of participants, employees and company information at all times
- Assist with the development of site and trial specific documents including but not limited to ICFs, source templates, recruitment plans, trial visit and participant dosing plans
- Thoroughly familiar with the protocol, case report form, informed consent, source documentation, patient diary (when applicable), study medication(s) and SOPs for the clinical trial
- Work with the Principal Investigator (PI) and Study Clinician to maintain high quality and participant safety
- Delegate study responsibilities as appropriate and ensure necessary training and qualifications of clinical trial team members
- Guide and oversee the clinical trial team in the conduct of the BOHEMIA clinical trial, according to the study protocol, ICH-GCP, local and international regulations and SOPs
- Ensure participant recruitment, screening and enrolment activities are conducted according to the study protocol, ICH-GCP guidelines, local regulations and requirements and SOPs
- Perform clinical procedures and assessments as required by the study protocol
- Dispense investigational product and instruct participants on usage and potential drug interactions as required
- Complete all documentation, paper and electronic in a timely manner as required per protocol to ensure data integrity
- Maintain responsibility for the Investigator Site File and archiving of thereof
- Provide project status updates and reports to CISM and the Sponsor as required
- Be present for all monitoring visits and attend all monitoring debrief meetings
- Risk identification and escalation to CISM and the Sponsor
- Issue identification and applicable escalation to CISM and the Sponsor
- Coordinate, manage and participate in clinical trial meetings with the site, community, CISM, Sponsor and others as required
- Provide training for collaborating physicians and clinic nurses on BOHEMIA protocol and investigational product.

Required qualifications
- MD degree
- Experience as Principal Investigator or Sub-investigator/Clinical Trial clinician on at least 1 clinical trial submitted to international regulatory agencies that was ICH-GCP compliant.
- Practical knowledge of clinical trial document processes and reporting of SAEs, non-compliances, annual reapproval, progress reports, CRFs, ICFs, etc.
- Current ICH-GCP certification
- Leadership and management of clinical trial teams
- Proficiency with Microsoft Office (Outlook, Word) and Web applications
- Exceptional organizational skills, attention to detail and follow through
- Excellent written and spoken English (must submit examples of written work)
- Willingness to live in Quelimane/Mopeia (Mozambique) or within reasonable travelling distance during the active period of the trial.

Required personal and interpersonal skills
- Ability to effectively and efficiently handle multiple tasks simultaneously with precision and adapt to changes in responsibilities and workloads
- Must be professional, possess a high degree of urgency and self-motivation, and

have a strong work ethic
- Results-oriented approach to problem solving
- High professional standards for clinical trial execution and reporting
- Accustomed to teamwork and willingness to contribute to elements outside the clinical trial scope
- Ability to work independently where necessary

Preferred
- Previous experience with malaria prevention clinical trials
- Previous experience in malaria-endemic countries
- Portuguese working proficiency

Conditions
- This position may require local and international travel for Institution, Sponsor and Funder led meetings.
- Compensation for this position will be based on the applicant's experience and qualifications.
- This position starts immediately

How to apply

Applicants must fill in the request form and attached the CV and a cover letter including the following reference: **CTI_BOHEMIA _Nov19**.
The closing date for the receipt of applications is **November, 27th 2019.**
Interviews will be done on a rolling basis; hiring of matching candidates might occur before the deadline.

Only shortlisted candidates will be contacted.

In ISGlobal we are committed to maintaining and developing a work environment in which the values and principles of our organization are respected and equal opportunities between women and men be promoted in each of the areas in which we operate, not tolerating discrimination based on criteria such as age, sex, marital status, race, ethnicity, disabilities, political leanings, religion or sexual orientation.