

**Request for proposal for 6 months of freelance monitoring services on the
BOHEMIA clinical trial**

Broad One Health Endectocide Malaria Intervention in Africa (BOHEMIA)

EXP 64 2021

Background:

The institution ISGlobal – Barcelona Institute for Global Health is a research centre 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 leverage on knowledge generation (research), transmission (training) and application (policy and global development).

ISGlobal is a WHO Collaborative Centre for Malaria Elimination and Eradication.

Malaria remains a public health problem across the developing world. After achieving remarkable advances from 2000 to 2015, the global fight against malaria has stalled. The World Malaria Report 2018 estimates an increase to 219 million cases in 2017 compared to 216 million in 2016. We are currently not on track to achieve the goals proposed by WHO in the Global Technical Strategy for Malaria 2016-2030 (GTS). Vector control, our most effective prevention strategy, is now doubly threatened by residual transmission and insecticide resistance. New tools are needed to control residual transmission, one of the key liabilities of vector control today.

Ivermectin is an endectocide, a drug with an excellent safety profile that can kill ecto- and endo-parasites, as well as mosquitoes fed on treated humans or animals.

Mass drug administration (MDA) of ivermectin to humans and/or livestock holds the potential to complement the malaria toolbox by tackling residual transmission and help overcoming insecticide resistance.

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 Africa with analysis of impact on infection incidence, as well as supporting entomological outcomes.

Trial design:

- A Phase III cluster-randomized, open-label, clinical trial to study the safety and efficacy of ivermectin mass drug administration to reduce malaria transmission in two African settings.
- The selected site for this contract is in Mopeia, Mozambique.
- **Primary Objective:** To determine the safety (in humans) and efficacy of ivermectin MDA (administered to humans or humans and livestock simultaneously) for the prevention of malaria.
- **Primary outcome:** Malaria incidence in a cohort of children followed prospectively in the cluster's core area for six months post first MDA round, an outcome chosen based on WHO's PPC for endectocides.
- **Number of participants:** Each cluster will include 300-400 people, of which 240-300 will be eligible for treatment and at 80-150 will be children eligible for follow-up. There will be 53-54 clusters per arm, resulting in inclusion of 45,000-48,000 participants to receive treatment or control and 2,000-3,000 children to be followed for six months.

Monitoring

Risk based monitoring of the trials shall be conducted by a team of qualified and experienced CRAs and shall be in accordance with a Monitoring Plan that clearly describes the strategy, methods, responsibilities, and requirements for monitoring the trials. ISGlobal SOPs will be followed.

Monitoring will be a combination of onsite visits of 10 days each and remote monitoring activities between visits.

Scope of services required:

The consultant will be part of a team of 4 Clinical Research Associates, and is required to conduct monitoring activities in accordance with the Monitoring Plan and ISGlobal SOPs. These activities include, but are not limited to:

- Ensuring that all trial activities are implemented according to project objectives and timelines
- Ensuring that monitoring activities are conducted in accordance with the study protocol, ICH-GCP (International Conference on Harmonization/ Good Clinical Practice), Monitoring Plan and SOPs
- Conducting a site initiation visit
- Monitoring of Informed Consent and Assent Forms
- Contributing to the management of the Trial Master File

- Monitoring Safety Events
- Reviewing participant diaries
- Monitoring of electronic participant visit data
- Conducting onsite pharmacy visits and drug accountability activities
- Conducting onsite laboratory visits and sample verification
- Monitoring the Investigator Site File for completeness
- Monitoring data queries and work with the site for resolution
- Maintaining a non-compliance log
- Writing monitoring reports for both onsite and remote monitoring visits
- Identifying areas for site staff training
- Problem identification and resolution
- Having a professional working relationship with the Sponsor and Site teams

Management of work and quality control

The successful candidates will report to the BOHEMIA Clinical Trial Manager who will direct and oversee all monitoring activities. Communication between the parties will consist of various formats including scheduled calls/meetings, ad hoc conversations, in person meetings at site monitoring visits, contact via electronic communication platforms and email.

Required qualifications

- University degree in Sciences (Biology, Pharmacy, Biomedical science or related field) or equivalent work experience
- At least 3 years of monitoring or quality assurance experience in clinical trials
- Experience working in rural environments is preferred
- Ability to travel to the Mopeia site in Mozambique for 10 working days at a time plus travel. Estimated 5 trips in 6 months
- Current GCP certificate
- Strong knowledge of written and spoken English is required; knowledge of Portuguese is an advantage
- Excellent computer skills: MS Word, Excel, Outlook software or equivalent
- Ability to work as part of a team and independently
- Self-motivated and goal oriented, able to meet deadlines
- Good communication skills
- Organisation and project management skills

Duration of Contract

- Fulltime (100% allocation) from 7 January 2022 – 15 July 2022

Payments

Payments are 30 days on receipt of an approved invoice of hours worked from the consultant. Hours are capped at 160 hours per month, and the total of hours invoiced for 6 months may not exceed 960.

Payment currency is USD (US Dollars).

The hourly rate will be commensurate with the candidate's experience and budget parameters.

Application process:

A cover letter and CVs must be submitted by email to the address licitaciones@isglobal.org and maryann.richardson@isglobal.org.

Please indicate in the cover letter that the application is for the six month contract

The deadline for submitting proposals will end on 15 December 2021.