

BOHEMIA

Broad One Health Endectocide-based Malaria Intervention in Africa Scope of work for data management and field app contractor

Background

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 and residual transmission. New tools are needed to control residual transmission, one of the key liabilities of vector control today and which openly challenges achievement of the GTS goals.

Ivermectin is an endectocide, a drug with excellent safety profile that can kill ecto- and endoparasites, 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 Tanzania and Mozambique with analysis of impact on infection incidence as well as supporting entomological outcomes.

Scope of work for project management contractor

The BOHEMIA project has complex data needs. ISGlobal is seeking a contractor to handle data management from the field to analysis. This includes development of a field-friendly data collection app for mobile devices, participation in design and maintenance of databases and creation of tailored dashboards. Guiding principles in the text below.



Data collection

The application:

BOHEMIA seeks specific data collection through a custom-made application, designed to run on both tablets and mobile phones. The application, should ideally be based on open-source data collection and storage software, and also have a browser-based component for use through a standard desktop.

Data entry:

We seek three modes of data entry:

- Tablet-based fieldworker / data entry clerk uses the "BOHEMIA" application to follow a
 questionnaire with explicit survey flow and validation protocol (see "Validation" section).
 (approximately 95% of cases)
- 2. Site manager uses the browser-based application to enter edge case data points or batch-processed entries. (approximately 4% of cases)
- 3. Centralized database manager manually enters or modifies entered data at the request of a site manager. (<1% of cases)

Language issues:

The "BOHEMIA" application's front-end should be in the language of the user. Back-end translation tables will be devised for every question and answer category. Upload should be done in the respective English translation.

On-device storage and upload:

Data entry should not rely on internet connectivity. Entries should be stored locally on the dataentry and uploaded upon WIFI connection with a pre-authenticated network.

Validation

Individual validation checks:

The "BOHEMIA" application should employ levels of validation to reduce data contamination including but not limited to: requiring the person entering data to explicitly confirm an entry if deemed to be unlikely, requiring a supervisor password for out of the norm cases, etc.

Aggregate validation checks:

Measures to reduce contamination caused by systematic errors should also be included

Storage and security

Storage:

A centralized database will be employed with backups generated regularly. Data tables will consist of one table per survey form, in addition to translation tables.

Security:

All work to comply with FDA regulatory requirements such as 21CFR Part 11 Local.



Real-time analysis and dashboards

Dynamic reporting:

Dashboards and dynamic reports should be written *a priori* and updated in real time. To include at least the following:

A <u>process-oriented</u> dashboard with up-to-date charts, tables, and tests which detail the current status of data collection.

A <u>content-oriented</u> dashboard with up-to-date reflection of the *content* of the data collected to allow for monitoring results in real time.

Study design and protocol adherence assistance

Study design:

The contractor (with support from the ISGlobal statistics team) will handle statistical and geospatial tasks (sample size, power calculations, distance and route approximations, etc.).

Protocol adherence:

Additionally, ISGlobal, through its contractors, will handle the iterative flow of data collection and data product generation.

Key points

- Measures to guarantee double data storage will be in place. Note that each site will host and own the national data.
- Android-compatible tablets/phones will be available at each site
- Assumption is all sites have at least semi-regular (weekly) internet access for data upload
- Surveys will contain clear question flow

Additional task: technical assistance and dynamic changes

Contractor is expected to provide technical assistance through the study implementation and data analysis process. Project ends in 2023. The nature of the project will require modifications after piloting and during data collection, also in response to request by ethics and advisory committees.

Budget

The program is subject to a stage-gating process with requirement to deliver critical milestones by Q4 2019 in order to carry on with the trials. The contractor is expected to work with the ISGlobal team during this first period for fees not exceeding US\$ 200.000.

Additionally, Technical support and follow on work it will be defined on a later stage subject to a separate public tender process.

Deliverables and timelines

- Joint work with study teams to develop data bases in parallel with protocols and questionnaires starting Q2 2019.
- Development of data collection app for census including validation steps by Q4 2019
- Development of BOHEMIA app including validation steps by Q2 2020
- Creation and formatting of databases by Q2 2020
- First version of dynamic dashboards by Q3 2020



Documentation to be provided by tenders

- Full written proposal including technical specification
- Detailed budget
- Examples of previous work including data collection tools, data bases, dashboards or other relevant works.
- Proof of previous international experience

Award procedure

ISGIobal Barcelona Institute for

The selection process will follow ISGlobal's SOPs. Relevant criteria for choosing a partner beyond economic offer are:

- Excellent track record of app and database development
- Previous international experience
- Previous field work in Africa
- Proven collaboration track with ISGlobal or consortium members

Payments

Payment will be milestone based. Milestones will be mutually agreed during contract negotiations.

Legal system for the contract

Essential obligations of the successful bidder will be as follows:

- Guarantee to act in the best practice and due diligence for the safety storage and security of the data, in compliance with the local and international applicable regulations.
- Guarantee absolute confidentiality of the documentation received, taking the due diligence
 not to disclose it, or use it in any way other than the purpose of this contract. Failure to
 comply with this obligation will automatically imply termination of the contract and will
 result in a claim by ISGlobal for damages that may have been inflicted.
- Guarantee and take responsibility for the technical quality of the works and services that develops and the consequences that may occur, by ISGlobal or for third parties, as a consequence of omissions, errors or inadequate methods in the execution of the contract.
- To carry out a strict-follow up in executing the work for the dynamic reporting.
- Deliver the works hired in the manner and terms hereby established.

This contract is considered a private contract and is subject to private law, governed by this Schedule, by the contract and documentation attached, and in everything not provided by the applicable civil and commercial legislation.

Place and date for submission

The economic proposals must be submitted by email to the address contrataciones@isglobal.org. The deadline for submitting proposals will end on March 8, 2019.