

Broad One Health Endectocide Malaria Intervention in Africa (BOHEMIA)

Request for proposal (RFP) for clinical trial investigational product for the BOHEMIA clinical trials

EXP_22_2019

ISGlobal invites you as a Service Provider to submit a proposal in response to this RFP for clinical trial investigational product/s in support of the BOHEMIA clinical trial.

Background:

The Barcelona Institute for Global Health – ISGlobal - 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), education and application (policy and global development).

ISGlobal is a WHO Collaborative Centre for Malaria Control, 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 219 M cases in 2017, an increase of 3 million cases compared to 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 and is the focus of the planned trial.

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 build demand, as well of quality product by facilitating manufacturer engagement as potential suppliers of quality, high volume/low cost product sufficient for malaria indication, should it prove successful.

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

Trial design:

- A double-blind, controlled, multicentre, superiority, cluster-randomized trial in two African countries to determine the effect of human ivermectin MDA, or human and livestock ivermectin MDA, on malaria infection incidence across two years
- Trials will be conducted under GCP with ethical/regulatory oversight
- Selected sites are in Dar es-Salam, Tanzania and Maputo, Mozambique
- Trial initiation is envisaged for January 2021 in Maputo, Mozambique, and March 2021 for Dar es-Salam, Tanzania
- Participant dosing occurs once a month for 3 months in each country during the malaria season

Number of participants:

- In Trial Year one, approximately 52 clusters in Mozambique and 72 clusters in Tanzania will be randomized in two arms, resulting in inclusion of approximately 45,000 participants >15kg to receive treatment or control. In Trial year two, approximately 65,000 participants will receive treatment or control.

Quantity of investigational product required:

Year 1

472,626 x Ivermectin 400mcg/kg active

472,626 x Ivermectin matching placebo

71,610 Albendazole 400mcg/kg active

71,610 x Albendazole matching placebo

Year 2

945,252 x Ivermectin 400mcg/kg active

472,626 x Ivermectin matching placebo

71,610 x Albendazole 400mcg/kg active

143,220 x Albendazole matching placebo

Scope of services required:

Manufacturing and shipping of ivermectin active to the clinical trial sites in Maputo, Mozambique and Dar es-Salam, Tanzania

Manufacturing and shipping of ivermectin placebo to the clinical trial sites in Maputo, Mozambique and Dar es-Salam, Tanzania

Manufacturing and shipping of albendazole active to the clinical trial sites in Maputo, Mozambique and Dar es-Salam, Tanzania

Manufacturing and shipping of albendazole placebo to the clinical trial sites in Maputo, Mozambique and Dar es-Salam, Tanzania

Or a combination of any of the above.

Quantities to be shipped each destination will be set according to the clinical trial needs in a later stage.

Format of proposal –The products for which you are submitting a proposal must be clearly indicated on the front page of your proposal

Criteria for Selection

Required:

- Current ability to manufacture and deliver selected products approved by a stringent regulatory authority (SRA) as defined by WHO in their Working document QAS/17.728/Rev.1, August 2017:
A regulatory authority which is:
 - a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
 - an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
 - a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015). “
- An organisation currently in the process of obtaining SRA approval by no later than 31 December 2019, for the facility and the products in your proposal
- Competitive generics pricing of product delivered to country
- Provision of required product information with this proposal for regulatory submission for clinical trial approval

Optional but highly preferable

- Interest in WHO prequalification for ivermectin (if relevant to your proposal)

Optional but preferable

- Becoming a supplier for subsequent scaled programs

Optional

- Capacity to ship the product blinded as instructed

Additionally, proposals will be assessed against the following criteria but not limited to:

• **Technical criteria**

- Project approach, methodology and planning
- Relevant licenses and accreditation
- Experience in manufacturing the product being proposed
- Experiences/skills, level of company representatives assigned to this project
- Quality and applicability of proposal presentation
- Customer references

• **Capacity to deliver**

- Reasonable timelines for production to meet BOHEMIA requirements
- Project management capabilities
- Past experience with similar work
- Profile of staff involved (CVs)

• **Financial criteria**

- Realistic costing of the proposal

Part A – Company overview

- Cover Letter and Signature Page signed by a representative of the company authorised to bind the company to the commitments in the proposal
- General information on the company including:
 - A brief history and size of the company

- Details of the products and services the company provides
- What distinguishes the company from its competitors
- A list of countries in which the company has registered offices
- A list of clinical trials by therapeutic indication and countries for which the company is manufacturing and shipping investigational product
- A list of countries in which the company is licensed/approved for the manufacturing and shipping of ivermectin/albendazole, the indication for which it is intended and the dosage
- Copies of relevant certification for the manufacturing facility, including SRA accreditation as a manufacturing facility
- 1 past and 2 current contactable references

Part B – Technical proposal

Detailed proposal explaining how your company's approach will enable the BOHEMIA team to meet project timelines and ensure quality results. Components should include, but not be limited to:

- Shipping of ivermectin/albendazole/placebos should be not later than August/September 2020. It might be in one or two shipments
- Current and planned stock levels of ivermectin and albendazole that could be supply with stock expiry dates no early than september 2022. Matching placebo for ivermectin and for albendazole, with expiry dates as appropriate for use in clinical trials year prior to 1 Sept 2021 and year 2 prior to Sept 2022.
- If the organisation does not currently have sufficient or planned available stock for ISGlobal, the processes and procedures your company will follow from securing API to delivering the investigational product to the clinical trial sites in Mozambique and Tanzania over the duration of the clinical trial. Please include start date of process and timeline to complete manufacture
- Shipping it's under the Delivery Duty Paid (DDP) Incoterms
- All operations should be conducted to current Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards. A Quality Agreement will be established with ISGlobal which also reserves the right to audit facilities, procedures and related documentation
- Current packaging options for the investigational product/s relevant to your proposal **AND** recommendations for optimal packaging for the BOHEMIA clinical trial, keeping in mind that product will be administered in rural areas by healthcare workers at participant homes
- Copies of all relevant licenses/accreditation to manufacture the investigational product/s required for the BOHEMIA clinical trial
- Certificates of analysis for the investigational product/s relevant to your proposal

- Stability data for the investigational product/s relevant to your proposal
- Bioequivalence data for the investigational product/s relevant to your proposal (if applicable)
- Copies of SRA accreditation for the API used for your products and FPP
- Clinical trial labelling options for the investigational product/s relevant to your proposal – please submit a draft label
- Recommendations for investigational product blinding
- Project staffing and CVs of key personnel for the project
- Draft project plan
- Please provide a list of your SOPs relevant to each step of the manufacturing, shipping and delivery process
- Propose your metrics for success
- Expression of interest in commercial supply of active product/s should the trial be a success. Please indicate if this is not of interest to you at this stage

Part C- Financial

- Please provide a detailed budget for your proposal including what percentage has been allocated to operating costs of the company
- Please present your proposed budget in USD (US Dollars) and apply pricing for non-profit organisations if possible. Please specify how non-profit pricing has been applied in your narrative.
- Please describe cost efficiencies and areas in which they have been applied in your narrative

Other:

ISGlobal reserves the right to:

- Reject any proposal without any obligation or liability to the potential service provider.
- Withdraw this RFP at any time before or after the submission of bids without any advance notice, explanation or reasons.
- Accept any proposal other than the lowest one
- Award a contract on the basis of initial proposals received without discussions for best and final offers
- Award all services to only one supplier or allocate them to different suppliers according to what ISGlobal will consider necessary
- Late submission proposals are subject to rejection
- ISGlobal reserves the right to request additional data, information, discussions or presentations to support their proposal. All bidders must be available to discuss details of their proposal during the RFP process
- All proposals should be submitted in an electronic format

Timelines:

Process steps	Responsible party	Timelines
Deadline to return the Non-Disclosure agreement	Service Provider	02 September 2019
Deadline to send Q&A to ISGlobal	Service Provider	04 September 2019
Consolidated ISGlobal response to Q&A	ISGlobal	10 September 2019
Deadline for proposal submission	ISGlobal	16 September 2019
Notification to pre-selected bidders	ISGlobal	23 September 2019
Bid Defence Meetings (if applicable)	ISGlobal	25 – 27 September 2019
Bidder selection	ISGlobal	30 September 2019
Project Start	Service Provider	On award

Questions:

All bidders may request further clarifications with regards to this RFP, by addressing questions in writing to the dedicated key contacts procurement.bohemia@isglobal.org by the date indicated in the above table.

In order to keep a fair bidding process, questions on the substance will only be answered in a document shared with all the bidders on the date indicated in the above table.