

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

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UPDATED REQUIREMENTS FOR ALBENDAZOLE PLACEBO PROCUREMENT

As part of the ongoing trial design and procurement process, it has become necessary to update this RFP for the procurement of the albendazole 400mg placebo tablets.

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 Unitaïd 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 Rufiji, Tanzania and Mopeia, Mozambique
- Trial initiation is envisaged for January 2021 in Mopeia, Mozambique, and March 2021 for Rufiji, Tanzania
- Participant dosing occurs once a month for 3 months in each country during the malaria season

The updated information is as follows:

Confirmation of trial duration:

The trials are conducted over a 3-month period during the rainy season in each country of year 1, and repeated in year 2.

Number of participants:

16,800 (48 clusters x 175 people treated = 8,400 per arm) randomized to human ivermectin + albendazole placebo (8400 participants) or albendazole plus ivermectin placebo (8400 participants) in year one and continuing in year two until end of study.

Quantity of investigational product required and delivery dates:

Year 1

- 28, 750 Albendazole 400mg placebo tablets for Mozambique
Delivery anticipated in Mozambique in October, latest November 2020 for use January – March 2021

- 28, 750 Albendazole 400mg placebo tablets for Tanzania
Delivery anticipated in Tanzania in October 2020, latest Jan 2021 (depending on available stability data) for use March – May 2021

Year 2

- 55, 000 Albendazole 400mg placebo tablets for Mozambique
Delivery anticipated in Mozambique in October 2021 for use January – March 2022
- 55, 000 Albendazole 400mg placebo tablets for Tanzania
Delivery anticipated in Tanzania in October 2021 for use March – May 2022

Other Considerations for the proposal:

ISGlobal have been unable to find a global provider of albendazole 400mg active tablets that are registered in both Mozambique and Tanzania that meet WHO requirements. It is therefore highly likely that the active albendazole 400mg tablets will be procured from local distributors.

This will probably result in two active tablets that differ in appearance and packaging.

The placebo tablets are required to match the in-country active products.

Proposal requirements:

If you have already submitted a proposal in response to the original RFP, please provide an updated costing and timelines, ensuring that your proposal still meets the Technical requirements as stipulated in section B below.

If this is your first submission, please provide the following:

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
- A list of clinical trials by therapeutic indication and countries for which the company is manufacturing placebo

Part B – Technical proposal

A 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:

- How your organisation will ensure that it has all the components required to manufacture the placebos in accordance with the BOHEMIA timelines. Please highlight and cost all components that would need to be purchased specifically for this project, or note if the equipment is currently available in your facility.
- Please list any information that will be required from the manufacturer of the active albendazole product, and the contingency plan with associated costs if the information is not provided within the required timeframes
- 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
- Copies of all relevant licenses/accreditation to manufacture the investigational product/s required for the BOHEMIA clinical trial in accordance with GMP
- Certificates of analysis for the placebo (if available and to be used for BOHEMIA) or state that this will be available prior to shipment
- Stability data for your placebo products (if available and to be used for BOHEMIA) or state that this will be available prior to shipment
- If stability data will be collected de novo for the BOHEMIA placebos, please provide the timepoints for the collection of the data and ensure it matches your product delivery commitments
- Draft project plan showing timelines from signing of contract in April 2020 to first delivery of product
- Please provide a list of your SOPs relevant to each step of the manufacturing, shipping and delivery process

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

Please note you will be required to sign a Non-Disclosure Agreement prior to receiving any further trial or active product information

Process	Date
Proposal submission deadline	31 March 2020
Project award	3 April 2020
Contract finalisation	15 April 2020

It is anticipated the project will commence as soon as the contract is signed.