Request for proposal for Safety services on the Broad One Health Endectocide Malaria Intervention in Africa (BOHEMIA) clinical trial

EXP_16_2019

Background

ISGlobal – the Barcelona Institute for Global Health -- is an international health research centre whose ultimate goal is to help close the gaps in health disparities between and within different regions of the world. For this, we focus on knowledge generation (research), training, and implementation (both policy and global development).

ISGlobal is a WHO Collaborative Centre for Malaria Control, Elimination and Eradication. Malaria remains a public health problem in endemic countries. 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.

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 demonstrating the efficacy of ivermectin against malaria to support a WHO policy recommendation, as well as by engaging country leaders and civil society in order to forge local ownership and create demand. In addition, to ensure the supply of high volume/low cost quality product it will be key to efficiently engage manufacturers.

Further information on the trial design will be supplied on receipt of a fully executed Non-Disclosure Agreement (NDA).

I. CONTENT OF THE WORK

Scope of services required

- Safety management plan
- Generation of CIOMS or MedWatch forms

- Medical support for Principal Investigators/Sub-Investigators primarily during the dosing and the week post dose period in the event they have questions relating to a SAE
- Medical assessment and MedDRA coding of all AEs and expedited safety reports
- Identification of any AESIs as specified in the protocol
- Expedited reporting to Regulatory Authorities and preparation of reports for sites as required for Ethics Committees
- Collation of SUSARs and notification to ISGlobal and sites for reporting
- Periodic safety reports (e.g PSURS)
- Trend analysis/signal detection
- Preparation of safety reports to DSMB
- Participation in the DSMB
- Other – please specify any additional services for ISGlobal consideration

Format of 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 of the company and size of 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 and number of clients
  - A list of clinical trials by phase, therapeutic indication and countries where the trial was/is conducted for which the company is providing safety services
  - Previous experience with cluster randomized trials for any intervention
  - 2 contactable references

Part B – Technical proposal

- Detailed description of the safety system, database and services proposed in the context of a trial of a known, licensed intervention
- Project staffing and CVs of key personnel for the project
- Confirmation that the safety database is ICH-GCP and 21 CFR Part 11 compliant
- SOPs for each step of the process
- Please provide a list of your SOPs
- Cost efficiencies
- Measuring success

Part C- Financial

- Please provide a detailed budget for your proposal including what percentage has been allocated to operating costs of the company
- Please provide the costing in USD (US Dollars)

II. ESSENTIAL CONTRACTUAL OBLIGATIONS

They will be considered as essential obligations of the successful bidder, the following:

a) 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.

b) 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, inadequate methods or incorrect conclusions in the execution of the contract.

c) To carry out a strict follow-up in carrying out the work of the report audit.

d) Deliver the works and reports hired in the manner and terms provided in the Bidding Document.

III. CONTRACT PERIOD

Safety start up activities will commence shortly after the award of the contract. The clinical trial will commence in December 2020 for 6 months and December 2021 for 6 months. The trial is based on the anticipated start of the malaria season in each country. Trial closeout will be completed by 2023.

The estimated start date of the contract is May 17, 2019.

IV. CIVIL LIABILITY POLICY

The company that is awarded the contract commits to have throughout the validity of the contract of a liability policy with coverage minimum of € 500,000.- per claim

V. ADVERTISING

The present contract will be published by announcement in the Contracting Profile of the entity on the website: www.isglobal.org

VI. PLACE AND DATE OF SUBMISSION OF PROPOSALS

The economic proposals must be submitted by email to the address licitaciones@isglobal.org
The deadline for submitting proposals will end on 17 May, at 12:00.

VII. LEGAL SYSTEM OF THE CONTRACT

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

VIII. EXPENDIENT OF RECRUITMENT, AWARD PROCEDURE OF THE CONTRACT AND DOCUMENTATION TO BE PROVIDED TENDERS

The contracting of the reference services will be awarded by the procedure envisaged in Section IX of the Internal Contracting Instructions of the entity. From the day of publication of the tender notice, interested companies can be obtained through the contractor's profile on the website www.isglobal.org the necessary documentation to prepare your proposals.

ISGlobal will evaluate proposals based on how well the responses demonstrate the company's ability to meet the needs and scope of services for this project as outlined in this RFP, as well as cost-effectiveness of the proposed strategy. ISGlobal will select the company based on:

- Merits and completeness of the proposed project plan and scope of services proposed
- Service-related experience
- Experience and qualifications of proposed staff
- Planned approach to meet the project's requirements as listed above
- Financial proposal including, but not limited to, discounts, service charges, and other charges

Depending on the number and quality of proposals received, ISGlobal may shortlist 2 potential vendors and request further information or a presentation by the individual company. The way forward to final selection will be communicated to all parties at the same time.

IX. PAYMENT METHOD

Payment will always be made under invoice and 30 days invoice date by bank transfer once the services have commenced and in accordance with the contractual agreement.

Barcelona, May 14, 2019