

REQUEST FOR PROPOSALS

SPECIFIC AND TECHNICAL CONDITIONS FOR THE CONTRACTING OF TWO SENIOR CLINICAL RESEARCH ASSOCIATES

(FILE NUM. 16-2023)

I. Purpose

The purpose of this Request for Proposals is to invite suppliers to submit proposals for the contracting of two Senior Clinical Researchers Associates to conduct monitoring services on the BOHEMIA Clinical Trial, one for a period of 14 months and another one for a period of 17 months.

II. Scope

Background

The Barcelona Institute for Global Health (ISGlobal) is a cutting-edge institute addressing global public health challenges through research, translation into policy and education. ISGlobal has a broad portfolio in communicable and non-communicable diseases including environmental and climate determinants, and applies a multidisciplinary scientific approach ranging from the molecular to the population level. Research is organized in the following main areas, Malaria and other Infectious Diseases, Maternal, Child and reproductive Health, Urban Health and Child and environmental health, Climate & Non-Communicable Diseases. ISGlobal is accredited with the Severo Ochoa distinction, a seal of excellence of the Spanish Science Ministry. The candidate will be working for the BOHEMIA project which aims at contributing to the global public health impact for malaria developing a complementary vector control strategy.

Object of the procurement

The BOHEMIA project is looking for two Senior Clinical Research Associates (CRA). The consultants will be part of a team of four CRA's, and will be required to conduct monitoring activities in accordance with the Monitoring Plan and ISGlobal SOPs.

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 Kwale, Kenya
- Primary Objective: To determine the safety (in humans) and efficacy of ivermectin MDA administered to humans 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 48 clusters per arm, resulting in inclusion of 25,000-28,000 participants to receive treatment or control and 3,000-3,500 children to be followed for six months.

III. Contract Responsible

The BOHEMIA Clinical Trial Manager will be responsible for all the technical aspects of the contract.

BOHEMIA Project Manager and the BOHEMIA Finance Manager will be responsible for the procurement, administrative and budget validation of the contract.

IV. 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.

V. Required qualifications

- University degree in Sciences (Biology, Pharmacy, Biomedical science or related field) or equivalent work experience
- At least 5 years of monitoring or quality assurance experience in clinical trials

- Experience working in rural environments is preferred
- Ability to travel to Kwale and Pongwe site in Kenya for 10 working days at a time plus travel. Estimated 2 to 4 trips in 14 months
- Current GCP certificate
- Strong knowledge of written and spoken English is required; knowledge of Swahili 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
- Organization and project management skills
- Preferably based in Kenya

VI. Period of execution and delivery of reports

The execution of the work will be carried out over a period of 14 to 17 months.

Start and end dates are variable and subject to change to adapt to the Clinical Trial period.

VII. Essential contractual obligations

- Utilize expertise to perform remote, onsite, and combination monitoring visits to support non-traditional monitoring model.
- Conduct SIV and COV
- Conducting onsite pharmacy visits and drug accountability activities
- Conducting onsite laboratory visits and sample verification
- For all visits create and maintain appropriate documentation regarding visit preparation, site management, monitoring visit findings and action plans.
- Submit timely visit reports, generating follow-up letters and other required study documentation.
- Ensure that the safety, rights, and well-being of human participants are being always protected in accordance with ICH-GCP and the protocol by continually assessing site performance of the trial.
- Train site on protocol and study related procedures and provide ongoing assessment of adherence and identifying any re-training needs.

- Ensure compliance with approved protocol/protocol amendments, standard operating procedures, (SOPs), GCP and applicable regulatory requirements.
- Build productive relationships with the site staff to oversee study integrity.
- Proactively utilize problem solving skills to identify risks and provide resolutions with the site staff. As needed escalate risks to Sponsor team.
- Evaluate data quality and integrity and drug accountability to ensure quality.
- Monitor Regulatory Documentation for completeness and quality

VIII. Duration and start date

The duration of the contracts will be 14 and 17 months respectively.

The estimated start date of the contract is May 2, 2023.

Full time (100% dedication).

Start and end dates are variable and subject to change to adapt to the Clinical Trial period.

IX. Estimated value

For the two senior consultants, the contract budget is set to a maximum amount of 163,680.00 US dollars (USD), excluding taxes and travel costs, with the following breakdown per consultant:

- 89,760.00 US dollars (USD) for the 17 months CRA, and
- 73,920.00 US dollars (USD) for the 14 months CRA.

Travel costs will be reimbursed by ISGlobal.

X. Method of payment

The CRAs will be paid on a monthly basis, at the monthly rate agreed upon at the time of contract signature.

Payments are 30 days on receipt of an approved invoice of days worked from the consultant.

Payment currency is USD (US dollars).

XI. Advertising

The present Request for Proposals document will be published in the Suppliers section of the contracting entity's website: <https://www.isglobal.org/en/contrataciones>.

XII. Procurement procedure:

The selection procedure will be made complying with the internal procurement regulations of the contracting entity, as provided in sections VIII and IX of the Procurement Manual.

XIII. Nature of the contract

This contract is considered a private contract and is subject to private law, governed by the contract and attached documentation, and by the applicable civil and commercial legislation.

XIV. Submission of proposals

Interested applicants are invited to submit a comprehensive proposal, addressing the needs described in the Request for Proposals document, to the following e-mail address: contrataciones@isglobal.org.

Proposals must be sent in one single consolidated document in PDF format.

The deadline for the submission of proposals is set on **April 14, 2023, at 6:00 PM.**

Barcelona, March 29, 2023