

SPECIFIC AND TECHNICAL CONDITIONS FOR

A Clinical Trial Manager to oversee all human subject research and clinical trial activities for the BOHEMIA project

(File 39/2022)

I. OBJECT

The present document (the "Pliego") to contract a Clinical Trial Manager well versed in GCP guidelines and clinical trial monitoring to support the BOHEMIA (Broad One-Health Endectocide-based Malaria Intervention in Africa) project in Mozambique and Kenya with the management of the clinical trials.

All the technical specifications contained in this document are considered to be part of the minimum requirements and do not exclude any other needs for compliance with the purpose of the service contracted.

II. CONTENT OF THE WORK

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. New tools are needed to control residual transmission, one of the key liabilities of vector control today. Ivermectin is an endectocide, a drug with 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.

BOHEMIA is a Unitaid funded, 5-year project and clinical trial that combines evidence generation and stakeholder engagement to create an enabling environment for ivermectin as a first-in-class endectocide for malaria prevention. Given that Ivermectin is being tested for a new indication, the project falls under the category of a clinical trial which therefore requires strict adherence to Good Clinical Practice (GCP) guidelines. Good clinical practice guidance produced by the International Council for Harmonisation (ICH) of technical requirements is applicable for registration of pharmaceuticals, medicines and healthcare products. Internationally scientific, ethical

and quality standards of GCP is essential for designing, conducting, performing, monitoring, auditing, recording, analysing and reporting clinical trials. It serves to protect integral rights and confidentiality of trial subjects along with ensuring the credibility and accuracy of reported data and results.

Scope of work

ISGlobal – Barcelona Institute for Global Health 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), transmission (training), and application (policy and global development).

The scope of work this service will include:

- Ensures that all human subject research activities that will be done under the BOHEMIA project are conducted under standards of Good Clinical Practices (GCP)/ICH as per ISGlobal’s SOPs. This will entail:
 - Ongoing discussions and advising with the site team, ISGlobal team, and monitors
 - Monitoring and reporting of non-compliance.
 - Work collaboratively with the QA officer, Chief Scientific Officer (CSO) and other positions (as needed) to evaluate clinical policies, practices, and SOPs, proposing changes where needed.
 - Work with CSO, QA officer, and Lead Clinical Research Associate (LCRA), to monitor study progress, and support analysis and evaluation of all data from clinical studies for progress reporting.

- Supports the clinical research teams at headquarters and site levels in the full spectrum of the trial including:
 - Protocol development
 - Obtaining ethical and regulatory approvals for the trial prior to study site initiation
 - Completing and advising site on submission documents, managing the master documents, obtaining IP information and compiling it in required format for regulatory submissions.
 - Review back translations to English of site documents to ensure correctness of translations.
 - Trial management activities from start up to close out, including: tracking, writing and reviewing of progress reports for all protocols.
 - Management of clinical trial monitors, including: planning of onsite monitoring activities, visit planning, formatting of database reports for remote monitoring, queries, actions, etc
 - Final review and approval of monitoring reports
- Review and approval of monitors’ timesheets and expenses
- Review and approval of pharmacovigilance invoices to monthly activities. This includes SAE monitoring, reporting in accordance with GCP, SMP, and study protocol.

- Verify that all subject research activities undertaken in field sites as part of the BOHEMIA project are conducted according to the standards of ICH-Good Clinical Practice, international and local regulations.
 - Advise CRAs and site team on what requires CAPAs, NtF, reporting, work to monitoring report
- Reviews and provides resolution to escalated issues identified as study risk
- Risk identification and escalation to the PI/CSO, when deemed necessary
- Coordinates, manages and participates in clinical trial meetings
- Provides project status updates and reports to the PI/CSO as required
- Issue identification and applicable escalation to the PI/CSO
- Participates in initiation visits and assists with HSR training of field staff.
- Attends consortium and other meetings as required. Presents data as required.
- Contribute to funder reports

All activities performed should be tracked and documented in activity reports due monthly.

III. PERSON RESPONSIBLE FOR THE CONTRACT (If Applicable)

ISGlobal will appoint a person responsible for relations with the CTM (the "Contract Responsible"), who will coordinate with the staff of the entity and who will channel communications between the two parties; however, other staff of the entity may contact the consultant directly when necessary.

IV. MANAGEMENT OF WORK AND QUALITY CONTROL

ISGlobal and the CTM will establish by common agreement a calendar of communications that will consist of bi-weekly or monthly progress calls. Regardless of these scheduled calls, the Contract Responsible and the project management team may meet at any time if any of the two parties considers it appropriate, depending on the progress of the work hired. At any meeting the responsible person may choose to bring additional participants from ISGlobal if considered convenient. Monthly reports will be provided by the consultant.

V. REQUIRED QUALIFICATIONS

The CTM personnel (or the Clinical Trial Manager or consultants) should meet these requirements;

- University degree in Sciences (Biomedical science or related field)
- At least 3 years of clinical monitoring experience in clinical trials
- Excellent management, project planning, and organizational skills
- Knowledge of written and spoken English is required; knowledge of project language, such as Spanish, Swahili or Portuguese is a strong plus
- Advanced knowledge of GCP and Legislation about Clinical Trials
- Excellent computer skills: MS Word, Excel, Outlook software or equivalent

- Demonstrated reporting skills
- Ability to effectively work both as a team member and independently
- Experience working in international environments is preferred
- Preferably, having a team leader spirit, team working, good communication skill and project management skills
- Ability to travel following a travel calendar but also at short notice (15 days)

Compensation for this position will be based on the applicant's experience and work plan.

VI. CONTRACT PERIOD

The duration of the contract will be of 18 months.

The estimated start date of the contract is August 1st, 2022 and the ending date is January 31st 2024.

VII. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT

The contract budget amounts to the maximum amount of

USD 105,000.00 excluding tax

The award amount will not exceed this budget in any case. The price of the contract, consequently, will be that to which it rises plus the corresponding Value Added Tax, in the case of non-exempt bidders, which must be included in the separate item.

VIII. ADVERTISING

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

IX. 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 22nd July 2022.

XII. 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.

XIII. 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 obtain the necessary documentation to prepare their proposals through the contractor's profile on the website www.isglobal.org.

XIV. PAYMENT METHOD

The CTM will provide activity reports along with invoices on a monthly basis. Payment will always be made under invoice and 30 days invoice date by bank transfer.

Barcelona, July 12th, 2022