ISGlobal Barcelona Institute for Global Health

SPECIFIC AND TECHNICAL CONDITIONS FOR

A Project Field Coordinator for monitoring activities on study sites of the GHIT Chagas-LAMP clinical study in Argentina, Bolivia and Paraguay

(File 23/2021)

I. OBJECT

The present document (the "Pliego") to contract a clinical study field coordinator (FC) to provide appropriate monitoring on the GHIT Chagas-LAMP project ("Field validation of *Trypanosoma cruzi*-LAMP: a molecular point-of-care test for the control of congenital Chagas disease") in Argentina, Bolivia and Paraguay.

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

Chagas disease, caused by the protozoan parasite *Trypanosoma cruzi*, affects ~7 million people, mostly in Latin America. Vector-borne transmission is on the way of being controlled in several countries, but vertical transmission remains an uncontrolled major public-health challenge. Remarkably, available drugs have a very high cure rate in *T. cruzi*-infected newborns if administered early upon infection, thus a timely diagnose is crucial for treatment success. However, the algorithm to detect congenital *T. cruzi* infection involves parasitological methods that lack sensitivity and a serological study must be performed several months later. In many endemic regions people live far from referral centers which entails that a large proportion of infants rarely go back for diagnosis confirmation and treatment, if infected. Consequently, they evolve to the chronic phase of the disease with the risk of developing severe manifestations. Molecular-based diagnostics have a very high sensitivity to detect congenital *T. cruzi* infections, but laboratories in those distant regions are not equipped to perform them. With the aim to provide a suitable point-of-care (POC) test for the timely diagnosis of congenital Chagas disease in these settings, we will validate the implementation of EIKEN *T. cruzi* loop-mediated isothermal amplification (LAMP) prototype in the field.

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).

One of ISGlobal´s research lines is the study of improved diagnostics for generalizing access to diagnosis and reducing the impact of Chagas disease in low-resource settings. In this context a clinical study will be carried out whereby point-of-care (POC) rapid diagnostic tests (RDTs) and Chagas-LAMP will be used alongside routine algorithms for the diagnosis of chronic and congenital infection by *T. cruzi*, which are those recommended by the WHO - PAHO. The diagnostic efficacy of such POC methodologies, their reliability and robustness, in comparison to currently available tools will be all assessed in this study.

ISGlobal is looking for a clinical study Field Coordinator (FC) who is experienced in conducting monitoring activities to ensure the quality of the research activities at study sites in Argentina, Bolivia and Paraguay. Among the monitoring visits at the sites there will be: 1) assessment and initiation visits, ii) interim visits, and iii) end-term visits.

The key deliverables are:

1. To prepare a monitoring plan and monitoring report forms;
2. To prepare forms of Standard Operational Procedures (SOPs) for all sites;
3. To ensure that site visits are conducted in accordance with the timelines agreed with the project coordinator (Barcelona Institute for Global Health, ISGlobal);
4. To ensure that monitoring activities are conducted in accordance with the study protocol and SOPs;
5. To verify that the working teams in all study sites are complying with the project activities and objectives, have adequate resources throughout the study period, and that the facilities, including laboratories, equipment and staff, are adequate to safely and properly conduct the study throughout the study period;
6. To verify that the study diagnostic reagents are sufficient and that their supply is sufficient throughout the study;
7. To arrange and confirm appointments of the visits with all relevant staff at the sites prior to the visits;
8. To conduct monitoring visits and provide written site monitoring report at the agreed time after the visit.

III. PERSON RESPONSIBLE FOR THE CONTRACT (If Applicable)

ISGlobal will appoint a FC person (the "Contract Responsible"), who will coordinate with the staff of the participating implementation entities (the parties), and who will channel communications between the project coordinator and the parties, as well as with any relevant stakeholders in the project implementation regions.

IV. MANAGEMENT OF WORK AND QUALITY CONTROL

ISGlobal and the FC will establish by common agreement a calendar of communications that will consist of weekly progress calls. Regardless of these scheduled calls, the FC will become part of the project core management team, encompassed by the Project Leader, the Scientific Officer, the Financial Officer and the Public Health Advisor, and may meet with them at any time if considered appropriate, depending on the progress of the work. At any meeting the responsible person may choose to bring additional participants from the project consortium if considered convenient. Monthly reports will be provided by the consultant.

V. REQUIRED QUALIFICATIONS

The FC should meet these requirements;

- University degree in Sciences (Biology, Pharmacy, Biomedical science or related field)
- At least 3 years of monitoring experience in clinical studies
- Excellent management, project planning, and organizational skills
- Knowledge of written and spoken Spanish is required; knowledge of English is a strong plus
- Experience working in the field in health projects, preferentially on Chagas disease
- 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. PERIOD OF EXECUTION AND DELIVERY OF THE REPORT

The execution of the work will be carried out through the 24 months of the project trial periods. The current agreement would cover the 24 months provided ISGlobal is successful in delivering the trial milestones.

VII. ESSENTIAL CONTRACTUAL OBLIGATIONS

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

1. Field Coordination
    - Ensure that all study activities are implemented according to project objectives and timelines.

- Work with the parties implementation teams and with the project management team to ensure definition of objectives and the setting of priorities

2. Clinical Study Monitoring
   - Locating and assessing the suitability of facilities at the study centers
   - Monitoring the clinical study throughout its duration
   - Perform initiation, intermediary and end-term visits at the study sites during the study
   - Writing the monitoring reports
   - Carrying out the surveillance of diagnostics availability on site
   - Supporting sites in fast solving any upcoming issues
   - Answering the discrepancy report forms
   - Having an efficient working relationship with the sites´ implementation teams and the project parties principal investigators

VIII. CONTRACT PERIOD

The duration of the contract will be of 24 months distributed throughout the 24 months of trial activities.

The estimated start date of the contract is April 16st, 2021.

IX. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT

The contract budget amounts to the maximum amount of

43.200 EUR excluding tax and travel costs

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.

X. ADVERTISING

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

XI. 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 15th April 2021.

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

Payment will always be made under monthly invoice and 30 days invoice date by bank transfer

Barcelona, April 7th, 2021