ISGlobal Barcelona Institute for Global Health

SPECIFIC AND TECHNICAL CONDITIONS FOR

A Contract Research Organization for clinical monitoring activities on study sites of the ICARIA clinical trials at study sites in Sierra Leone

(File 35/2019)

I. OBJECT OF THE SUBJECT

The present document (the "Pliego") is intended to contract a Contract Research Organization for clinical monitoring purpose.

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

Findings from recent reports on mass drug administration of azithromycin (AZi) for trachoma control in SSA suggest that AZi administration at certain intervals within the first 2 years of life may be a strategy to reduce child mortality. However, despite the potential benefit of this intervention several fundamental scientific questions need to be answered before it can be recommended for large-scale implementation. To provide the evidence needed to inform policy and practice and to accelerate the implementation of this intervention, a large-scale clinical trial on the impact on all-cause mortality up to 18 months of age of AZi administration through the World Health Organisation (WHO) Expanded Program on Immunisation (EPI) will be carried out in Sierra Leone.

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 clinical research lines the study of maternal, infant and reproductive infectious diseases that affect women and children in low-resource countries, including malaria in pregnancy and in childhood. In this context an individually randomised, placebo-controlled clinical trial will be carried out with a factorial design whereby AZi will be administered alongside routine preventive health interventions of the EPI, such as immunisations and Intermittent Preventive Treatment in infants (IPTi), which is recommended by the WHO for malaria prevention in this age group. The potential

development of antibiotic resistance, the interactions with routine immunisations, the safety and the impact on the health system of AZi administration will be all assessed in this trial.

ISGlobal is looking for a contract research organization (CRO) with clinical research associates who are experienced in conducting clinical monitoring activities to ensure the quality of the research activities at study sites in Sierra Leone. Three types of trial monitoring visits at the sites will be performed before and during the conduction of the trial: 1) Initiation visits, ii) Interim visits and iii) Close-out visits.

The key deliverables are:

1. To prepare a monitoring plan and monitoring report forms;
2. To prepare Monitoring Guidelines and review CRF Completion Guidelines in the form of SOP for all sites;
3. To ensure that site visits are conducted in accordance with the timelines agreed with the sponsor (Barcelona Institute for Global Health, ISGlobal);
4. To ensure that monitoring activities are conducted in accordance with the study protocol, ICH-GCP (International Conference on Harmonization/ Good Clinical Practice) and SOPs;
5. To verify that the investigator has adequate qualifications and resources throughout the trial period, and that the facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial throughout the trial period;
6. To verify that the study drug storage time and conditions are sufficient and that drug supplies are sufficient throughout the trial;
7. To arrange and confirm appointments of the visits with all relevant staff at the sites prior to the visits;
8. To conduct monitoring visit 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 person responsible for relations with the CRO (the "Contract Responsible"), who will coordinate with the staff of the entity and who will channel communications between the two parties.

IV. MANAGEMENT OF WORK AND QUALITY CONTROL

ISGlobal and the CRO project coordinator 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 CRO personnel (or the Clinical Research Associates or consultants) should meet these requirements;

- University degree in Sciences (Biology, Pharmacy, 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 Kreo or other local languages, Spanish, 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. PERIOD OF EXECUTION AND DELIVERY OF THE REPORT

The execution of the work will be carried out through the 36 months of the project trial periods. The current agreement would cover the 36 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. Trial Coordination
   - Ensure that all trial activities are implemented according to project objectives and timelines.
   - Work with In Country Technical Coordinator and Project Management Team to ensure definition of objectives and the setting of priorities
2. Trial Clinical Monitoring
   - Locating and assessing the suitability of facilities at the study centers
   - Monitoring the clinical trial throughout its duration
   - Perform initiation visit at the study sites before trial´s start
   - Closing down study centers on completion of the trials
   - Writing the monitoring reports
   - Carrying out the medical product accountability on site
   - Supporting sites in updating the clinical trial file
   - Answering the discrepancy report forms

- Having an efficient working relationship with the sites´ investigator´s team

VIII. CONTRACT PERIOD

The duration of the contract will be of 36 months distributed throughout the 36 months of trial activities.

The estimated start date of the contract is April 1st, 2019.

IX. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT

The contract budget amounts to the maximum amount of

USD 550,000.00 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.

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 29th February 2020.

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 CRO will be providing periodically reports on travel expenses incurred due to trial monitoring activity alongside with invoices. Payment will always be made under invoice and 30 days invoice date by bank transfer:

First payment: 20%
Year 1 payment: 20%
Year 2 payment: 20%
Year 3 payment: 20%

Final payment upon completion of work: 20%

Barcelona, January 10th, 2020