ISGlobal Barcelona Institute for Global Health

MONITORING SERVICES FOR A CLINICAL TRIAL

EXP_17_2019

Background

The Barcelona Institute for Global Health, ISGlobal, is an innovative alliance between academic, government, and philanthropic institutions to contribute to the efforts undertaken by the international community to address the challenges in global health.

ISGlobal is coordinating a clinical research development of a fixed-dose co-formulation of ivermectin and albendazole towards the interruption of transmission of soil-transmitted helminths. This development includes the execution of two clinical trials- IVERKID and ALIVE detailed in Annex 1.

ISGlobal is looking for a Contract Research Organisation (CRO) to provide adequate monitoring as determined in line with the ICH Harmonised Tripartite Guidelines for Good Clinical Practice for the execution of the above-mentioned clinical trials.

I. CONTENT OF THE WORK

Scope of services required

The CRO assigned will report to ISGlobal. The main tasks include:

1. Trial Master File (TMF) and Investigators Folder (IF) set-up and other in-house activities such as review of case report forms.
2. Site initiation and training visits
3. Interim monitoring visits
4. Close-out visit
5. Operational oversight

Monitoring visits includes preparation of the visit, follow-up, report writing and off-site monitoring and follow-up.

Proposal monitoring

The proposal to be presented by the CRO should include the years of experience by the CRO in clinical trial management as well as experience in Africa and experience with neglected tropical diseases. The proposal should include the professional rate for one full time equivalent (1 FTE) of a qualified monitor/CRA with at least 2 years of monitoring experience. The proposal should include detail of the scope of service that can be provided to ISGlobal and an estimate of the pass through costs associated.

ISGlobal will hold regular meetings/teleconferences with the CRO (operational manager and CRA) to ensure high quality management.

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

The CRO activities are estimated to start in July 2019 through to 31st August 2021.

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

IV. ADVERTISING

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

V. 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 19 June, at 12:00 noon.

VI. 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.

VII. 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 Request for Proposal (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.

VIII. 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, June 5, 2019

Annex 1

Acronym:	IVERKID
Title:	An open, non-blinded, dose-escalation clinical trial for assessing the safety and tolerability of high-dose of ivermectin (400 µg/kg and 600 µg/kg) in a single-dose and three- days regimes in paediatric population.
Study Description:	An exploratory safety and pharmacokinetic study including dose escalation in *Trichuris trichura, Strongyloides stercoralis*, *Ascaris lumbricoides* or scabies infected paediatric population weighting 15 to 24 kg. Eight hundred and fifty (850) school-aged children are expected to be screened at participating schools to achieve this the estimated sample size of 96 participants.
Trials site:	Unicentric trial to be performed at Centro de investigação em Saúde da Manhiça (CISM) in Mozambique
Trial duration:	6 months
Participant Duration:	For each individual participant, the time to complete all study visits will be approximately 1 month.
Monitoring visits estimated	1 initiation visit 9 interim monitoring visit 1 close-out visit Monitoring activities from pre-study to close of study will take approximately 9 months

Acronym:	ALIVE
Title:	A Single-Blinded, Randomized, Multi-Centre, Parallel-Group, Active-Controlled, Superiority Study to Evaluate the Efficacy and Safety of a Single Day or 3-day Single Dose of an ALBENDAZOLE-IVERMECTIN Co-formulation vs ALBENDAZOLE for the Treatment of Soil-Transmitted Helminth Infections (*Trichuris trichiura*, hookworm, *Strongyloides stercoralis*) in Paediatric and Young Adult Subjects.
Study Description:	A multi-centre, 3-arm, parallel, open-label, individually randomised, phase III trial to compare safety and efficacy of the active control arm (current standard of care) against 2 experimental arms for the treatment of *T. trichiura*, hookworm and *S. stercoralis*, in children aged between 5-18 years in three sub-Saharan African countries (Ethiopia, Kenya and Mozambique). Allocation of participants to study arms will be done by block randomization and stratified by country. Treatment allocation for each study participant will be concealed in opaque sealed envelope that will be opened only after enrolment. Study participants will be assigned a unique study number linked to the allocated treatment group. This trial comprises of a screening phase, an enrolment phase, a treatment phase, a post-treatment phase with follow-up visits, and early withdrawal/end-of-study evaluations.
Phase:	Phase III
Trials sites	School based recruitment in primary and secondary schools in Ethiopia, Kenya and Mozambique.
Trial Duration:	18 months from recruitment expected to start in March 2020
Participant Duration:	For each individual participant, the time to complete all study visits will be approximately 1 month.
Monitoring visits estimated	3 Initiation visits (1 per site) 24 to 30 Interim monitoring (8 to 10 per site) These could increase or decrease depending on site performance and query resolution. 3 Close out visits (1 per site)