

MAMAH Clinical Site Monitor

EXP_26_2019

Background

The Barcelona Institute for Global Health, ISGlobal, is the fruit of 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 provides a hub of excellence dedicated to scientific research and the provision of health care. The institute, which originated in a joint initiative of the Hospital Clínic de Barcelona and the University of Barcelona, has amassed over 30 years of experience in the field of global health. The pivotal mechanism of its work model is the transfer of knowledge generated by scientific research to practice, a task undertaken by the Research, Training and Policy and Global Development departments. Its ultimate goal is to help close the gaps in health disparities between and within different regions of the world.

The Project

Malaria infection during pregnancy is an important driver of maternal and neonatal health especially among HIV-infected women. In Africa, at least one million pregnancies are co-infected with malaria and HIV annually. The interaction between the two infections is particularly deleterious in pregnancy, leading to increased risk of malaria and HIV viral load, which may increase the frequency of mother to child transmission of HIV (MTCT-HIV). Intermittent preventive treatment in pregnancy (IPTp) with sulphadoxine-pyrimethamine (SP) is recommended for malaria prevention in HIV-uninfected women but it is contraindicated in those HIV-infected on cotrimoxazole prophylaxis (CTXp) due to potential adverse effects. A recent EDCTP-funded trial showed that an effective antimalarial added to CTXp and long-lasting insecticide treated nets (LLITNs) in HIV-infected pregnant women improves malaria prevention and maternal health. However, the antimalarial used (mefloquine) was not well tolerated and it was associated with an increase in HIV viral load at delivery and a two-fold increased risk of MTCT-HIV. These findings highlight the need to find alternative drugs with better tolerability and safety profile to prevent malaria in this vulnerable group and to further study the pharmacological interactions between antimalarials and antiretrovirals (ARVs).

Dihydroartemisinin-piperaquine (DHA-PPQ), because of its long half-life and good tolerability constitutes one of the best candidates for IPTp in HIV-infected pregnant women. However, there is limited information on the pharmacokinetics (PK) of DHA-PPQ with concomitant use of ARVs and CTX, particularly in pregnant women. A randomized double blind placebo-controlled trial to evaluate the safety and efficacy of DHA-PPQ for IPTp in HIVinfected pregnant women receiving CTXp and using LLITNs will be conducted in two sub-Saharan countries where malaria and HIV infection are moderately to highly prevalent. In addition, the possibility for a pharmacokinetic interaction between DHA-PPQ and ARVs will be assessed in a sub-sample of participants. Women will receive ARV therapy according to national guidelines and their infants will be followed until one year of age to evaluate the impact of DHA-PPQ on MTCT-HIV.

The findings of this project will be relevant for the control of two of the most important poverty-related diseases (PRDs), in one of the most vulnerable groups, HIV-infected pregnant women exposed to malaria.

In order to expand the currently limited information on DHA-PPQ PK, ISGlobal is seeking a specific service provider for the assessment of the cardiac safety of PK sub-study participants.

I. OBJECT OF THE SUBJECT

The present document is intended to contract an external consultant or CRO to perform as Clinical Monitor to ensure the successful implementation and quality of the 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

KEY RESPONSIBILITIES:

- Ensure timely and quality monitoring of the clinical trial and achievement of the established objectives.
- Ensure efficient coordination of the clinical monitoring procedures

SPECIFIC DUTIES:

1. Trial Coordination

- Ensure that all trial activities are implemented according to project objectives and timelines.
- Work with Project Manager 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 centres
- Monitoring the clinical trial throughout its duration
- Perform, if necessary, initiation visit at the study sites before trial's start
- Closing down study centres on completion of the trials
- Writing the monitoring reports
- Carrying out the medical products accountability on site
- Supporting sites to keeping updated the clinical trial file
- Answering the discrepancy report forms
- Having an efficient relationship with the sites' investigator's team

REQUIRED QUALIFICATIONS

The CRO personnel (or the consultant) 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 Spanish, Catalan, French 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 international environments is preferred
- Preferably, having a team leader spirit, team working, good communication skills and Project management skills
- Ability to travel following a travel calendar but also at short notice (15 days)

III. 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.

IV. CONTRACT PERIOD

The duration of the contract will cover the clinical trial lifetime (around 30 months)

The estimated start date of the contract is September 2019

V. ADVERTISING

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

VI. 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 July 12, at 12:00.

VII. 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.

VIII. 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 audit 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.

IX. 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. Periodicity of payments will be agreed with the selected consultant or institution.

Barcelona, July 1st, 2019