MAMAH PHARMACOKINETICS SUB-STUDY - CARDIOSAFETY ASSESSMENT

EXP_21_2019

Background

ISGlobal – the Barcelona Institute for Global Health -- is an international health research centre whose ultimate goal is to help close the gaps in health disparities between and within different regions of the world. For this, we focus on knowledge generation (research), training, and implementation (both policy and global development).

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 blinded placebo-controlled trial to evaluate the safety and efficacy of DHA-PPQ for IPTp in HIV infected 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

The present document is intended to contract a consultant or entity to correlate changes in the electrocardiograms (ECG) with drug levels through monitoring cardiac safety signs of study participants by performing ECGs before, during and after drug administration.

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

Main activities

- Preparation of the study documentation (such us the Scope of Work, ECG User Manual, Communication Plan, material for the site training, etc.)
- Activate the e-learning platform for the study site training
- Provide the necessary technology (including software-licenced ECG devices and shipment)
- Provide technical support
- Create the cardiac safety database (including management and storage of data)
- Perform ECG data collection
- Analysis of quantitative and qualitative ECG data
- Deliverance of the appropriate reports

Requirements

- Experts in cardio safety

- Large expertise in malaria research
- At least 10 years' experience in clinical trials' services
- Experience working in EDCTP funded projects
- Able to give technical support with teams located overseas

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 equal the duration of the MAMAH pharmacokinetics substudy, estimated in 20 months, which will depend on the recruitment rates of the study subjects.

The estimated start date of the contract is October 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 21st June, 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, June 12th, 2019