

**SPECIFICATION OF SPECIFIC AND TECHNICAL CONDITIONS FOR
PROCUREMENT OF CLINICAL TRIAL INSURANCE FOR THE ICARIA PROJECT
CLINICAL TRIAL**

(File 02/2020)

I. OBJECT

The present document (the "Pliego") is intended to contract a clinical trial insurance company to provide appropriate insurance cover to participants on the ICARIA clinical trial.

All the technical specifications contained in the Specifications are considered of minimum requirements and do not exclude any other necessary for compliance the purpose of the service contracted.

II. CONTENT OF THE WORK

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 azithromycin (AZi) will be administered alongside routine preventive health interventions of the Expanded Program of Immunization (EPI), such as immunisations and Intermittent Preventive Treatment in infants with Sulphadoxine-Pyrimethamine (IPTi-SP), which is recommended by the World Health Organization (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.

The project ICARIA is a Gates Foundation funded, 5-year project that aims to provide evidence for planning a large-scale implementation with azithromycin in sub-Saharan Africa countries with high child mortality.

The trial will consist of a Phase III individually randomized, double blinded placebo-controlled superiority trial in infants exposed to malaria and high mortality burden.

The trial has been designed as an individually randomized double blind placebo-controlled superiority trial with a factorial design to evaluate the impact of adding AZi to IPTi-SP scheme administered through the EPI on all-cause mortality at 18 months of age.

There will be four study arms. Following the Sierra Leone's EPI scheme, infants will be recruited when attending health facilities for the Penta-1 vaccination and individually randomised to one of the following study groups:

1. AZi at Penta-1 visit, IPTi-SP at Penta-2 and Penta-3 visits, AZi plus IPTi-SP at measles visit at 9 months of age and placebo-placebo at measles visit at 15 months of age (n=4,729)
2. AZi at Penta-1 vaccine visit, IPTi-SP at Penta-2 visit and Penta-3 visit, AZi plus IPTi-SP at measles 1 visit and AZi plus IPTi-SP at measles 2 visit at 15 months of age (n=4,729)
3. Placebo at Penta-1 visit, IPTi-SP at Penta-2 and Penta-3 visits, placebo plus IPTi-SP at measles visit at 9 months of age and placebo-placebo at measles visit at 15 months of age (n=4,729).
4. Placebo at Penta-1 visit, IPTi-SP at Penta-2 and Penta-3 visits, placebo plus IPTi-SP at measles visit at 9 and at 15 months of age (n=4,729)

Participants

- A sample size of 18,916 infants will be recruited throughout the 36-month trial period.
- The study population will be infants attending EPI services for Penta 1 vaccine administration at 6 weeks of age.

Inclusion criteria

- Parents/guardians have signed the informed consent
- Permanent residence in the study area-health facility catchment area
- Without known allergies to or contraindications to macrolides
- Without known allergies to or contraindications to SP
- Agreement to complete the EPI scheme at the recruitment health facility
- Parents/guardians agree to participate

Exclusion criteria

- Residence outside the study area or planning to move out in the following 12 months from enrolment
- Known history of allergy or contraindications to macrolides and/or SP
- Known history of allergy or contraindications to SP

- With signs of any acute illness at the time of recruitment
- Participating in other intervention studies

ISGlobal is looking for:

- A clinical trial insurance company that is able to provide appropriate cover for participants on the ICARIA clinical trial in Sierra Leone for the duration of the study.
- The company must be registered as an insurance provider with the Sierra Leone Insurance Regulatory Authority.
- The insurance cover should meet local regulatory requirements.

III. INSURANCE COMPANY RESPONSIBLE FOR THE CONTRACT

ISGlobal will appoint a company responsible for providing appropriate clinical trial insurance for participants on the ICARIA clinical trial as documented in the clinical trial insurance policy.

IV. PERIOD OF COVERAGE

The insurance policy shall be valid for the duration of the clinical trial.

V. ESSENTIAL CONTRACTUAL OBLIGATIONS

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

- a) To provide appropriate insurance cover for ICARIA clinical trial participants based on a fair risk assessment of the ICARIA clinical trial protocol in accordance with local and international regulations and documented in a clinical trial insurance policy.
- b) To evaluate all insurance claims in a fair and expedited manner in accordance with the insurance policy.
- c) To reimburse successful claims in accordance with the insurance policy requirements and timelines.
- d) To provide ISGlobal with detailed feedback on how decisions were made to accept or reject any claims submitted.

VI. CONTRACT PERIOD

The duration of the contract will be the duration for the duration of the trial plus the following year i.e. corresponding period of claim.

The estimated start date of the contract is 1 April 2020.

VII. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT

Best value for money - proposals will be evaluated on individual merits.

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 as a separate item.

VIII. ADVERTISING

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

IX. PLACE AND DATE OF SUBMISSION OF PROPOSALS

The economic proposals must be submitted by email to the address procurement.

haily.chen@isglobal.org

The deadline for submitting proposals will end on 24th February 2020.

X. 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.

XI EXPEDIENT 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.

XII. PAYMENT METHOD

Payment will always be made under invoice and in accordance with policy requirements.

Barcelona, February 6th, 2020