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

(File 31/2019)**
**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 BOHEMIA 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). ISGlobal is a WHO Collaborative Center for Malaria Elimination and Eradication.

Malaria remains a public health problem across the developing world. After achieving remarkable advances from 2000 to 2015, the global fight against malaria has stalled. The World Malaria Report 2018 estimates 219 M cases in 2017, an increase of 3 million cases compared to 2016. We are currently not on track to achieve the goals proposed by WHO in the Global Technical Strategy for Malaria 2016-2030 (GTS). Vector control, our most effective prevention strategy, is now doubly threatened by residual transmission and insecticide resistance. New tools are needed to control residual transmission, one of the key liabilities of vector control today.

Ivermectin is an endectocide, a drug with an excellent safety profile that can kill ecto- and endo-parasites, as well as mosquitoes fed on treated humans or animals. Mass drug administration (MDA) of ivermectin to humans and/or livestock holds the potential to complement the malaria toolbox by tackling residual transmission and help overcoming insecticide resistance and is the focus of the planned trial.

The project BOHEMIA is a Unitaid funded, 4-year project that combines evidence generation and stakeholder engagement to create an enabling environment for ivermectin as a first-in-class endectocide for malaria prevention.

Evidence generation will consist of a Phase III cluster-randomized, placebo-controlled clinical trial to study the safety and efficacy of ivermectin mass drug administration to reduce malaria transmission in two African settings

The trial is a cluster randomized trial using a mass drug administration (MDA) strategy, therefore randomization occurs at village and not individual level.

ISGlobal is testing an additional indication for approved ivermectin oral tablets. The proposed clinical studies will use Stromectol® ivermectin purchased from Merck.

There are two human treatment arms:

1. Ivermectin + albendazole placebo
2. Albendazole + ivermectin placebo

Participants will receive a single dose of trial treatment for 3 consecutive months during the rainy season over two consecutive years. The targeted dosing period for Mozambique is Jan-Mar 2021 and 2022, and Mar-May 2021 and 2022 for Tanzania.

**Number of participants**

* Year 1 – 17 000 participants receiving treatment in each country
* Year 2 – 26 000 participants receiving treatment in each country
* Children in Mozambique enrolled in the efficacy cohort will only receive trial treatment if their weight is ≥15kg
* Children in Tanzania weighing ≥15kg are eligible for treatment and may thus form part of both the safety and efficacy cohorts.

**Exclusion criteria**

* + Known hypersensitivity to ivermectin or albendazole
	+ Risk of Loa as assessed by travel history to Angola, Cameroon, Chad, Central African Republic, Congo, DR Congo, Equatorial Guinea, Ethiopia, Gabon, Nigeria or Sudan
	+ Pregnant women
	+ Lactating women in the first week postpartum
	+ Children < 15 kg
	+ Currently participating in another clinical trial
	+ Unwilling to provide written informed consent or assent
	+ Unwilling to adhere to trial visits and/or procedures
	+ Severely ill either self-reported or in the eyes of the investigator, e.g. defined as need for clinical care, or active or progressive disease interfering with activities of daily living. If in doubt, these criteria can be confirmed after a call with the site PI/MD/safety officer
	+ Currently under treatment with inhibitors of CYP3A or P-gp or other drugs that can interfere with the trial treatment.

ISGlobal is looking for:

* A clinical trial insurance company that is able to provide appropriate cover for participants on the BOHEMIA clinical trial in Mozambique and Tanzania for the duration of the study.
* The company must be registered as an insurance provider with the Tanzanian 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 BOHEMIA 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 BOHEMIA clinical trial participants based on a fair risk assessment of the BOHEMIA 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 of the clinical trial over a period of two years.

The estimated start date of the contract is 1 January 2021.

**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](http://www.isglobal.org)

**IX. PLACE AND DATE OF SUBMISSION OF PROPOSALS**

The economic proposals must be submitted by email to the address procurement.bohemia@isglobal.org
The deadline for submitting proposals will end on 20 Dec, at 12:00.

**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 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.

**XII. PAYMENT METHOD**

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

Barcelona, December 05, 2019