

## SPECIFIC AND TECHNICAL CONDITIONS FOR

**A Contract Laboratory Organization for pharmacokinetics analyses for the phase II component of the ALIVE clinical trial, in the context of the STOP-2 project.**

(File 22/2021)

### I. OBJECT

The present document (the "Pliego") to contract a Contract Laboratory Organization to perform the pharmacokinetics analysis for the phase II component of the ALIVE clinical trial, in the context of the STOP-2 project.

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

The current World Health Organization (WHO) control strategy for soil-transmitted helminths (STH) emphasizes morbidity control through mass drug administrations (MDA) with albendazole or mebendazole, targeting pre-school and school-aged children and women of reproductive age in endemic areas. Increasing concerns have been raised about the success of these monotherapeutic strategies: 1) while albendazole is still efficacious against *Ascaris lumbricoides* and hookworm, a low and decreasing efficacy against *Trichuris trichiura* is observed, and none of these strategies is effective against *Strongyloides stercoralis* and 2) the use of widespread monotherapy could lead to the emergence of albendazole resistance.

Ivermectin has shown an enhanced activity against *T. trichiura* when combined with albendazole and it is considered the drug of choice against strongyloidiasis and other parasitic infections. Adding ivermectin to albendazole would increase efficacy of the interventions and decrease the possibility of emergence of resistance, as recently suggested by WHO.

#### 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 is the study of parasitic diseases and neglected tropical diseases, particularly in low- and middle-income countries, including soil-transmitted helminths. In this context, a clinical trial will be executed evaluating safety and efficacy of an **ivermectin and albendazole** co-formulation for the treatment of soil-transmitted helminths. The clinical trial also contemplates a component on pharmacokinetics of ivermectin and albendazole and their metabolites. The following determinations are necessary:  **$C_{max}$ ,  $T_{max}$  y AUC** for a total of **628 blood samples** collected with **Mitra<sup>®</sup> devices**. These determinations must be conducted following adequate international regulations: FDA, EMA, ICH and GLP. For more information, please contact ISGlobal. Aside from the sample analysis, the proposal must include the feasibility, development and validation of methods.

ISGlobal is looking for a Contract Laboratory Organization who is experienced in conducting pharmacokinetics analysis for clinical trials for registration that will perform the determination of ivermectin and albendazole in human blood samples collected with Mitra<sup>®</sup> Devices. These samples will be stored at room temperature.

The key deliverables are:

- Report on feasibility of methods
- Report on development of methods
- Report on validation of methods
- Final report on sample analysis

### III. REQUIRED QUALIFICATIONS

The Contract Laboratory Organization should meet these requirements:

- Experience in working with albendazole and ivermectin and its metabolites
- Experience in working with samples collected with dry bloodspots or volumetric absorptive micro sampling (VAMS)
- Production of study reports in English
- Following international regulations from FDA, EMA, ICH and GLP.

### IV. PERIOD OF EXECUTION AND DELIVERY OF THE REPORT

The execution of the work will be carried out after the recruitment and follow up of the clinical trial participants, that is expected to take 4 months, starting in September 2021. The final report is expected to be delivered within 4 months after completion of the trial.



## V. ESSENTIAL CONTRACTUAL OBLIGATIONS

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

- Evaluation of pharmacokinetics of albendazole, albendazole sulfoxide, ivermectin B1a and ivermectin B1b in all study samples.
- Evaluation of pharmacokinetics of albendazole, albendazole sulfoxide, ivermectin B1a and ivermectin B1b in ISR.
- Production of a final report with detailed results of the aforementioned evaluations in English.

## VI. CONTRACT PERIOD

Contractual agreement to be executed ASAP and will terminate after completion of the analysis and report on the PK analysis.

## VII. BUDGET, PRICE AND ESTIMATED VALUE OF THE CONTRACT

The contract budget amounts to the maximum amount of

**100,000.00 EUR including tax**

The award amount will not exceed this budget in any case. 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 in the 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 [licitaciones@isglobal.org](mailto:licitaciones@isglobal.org)

The deadline for submitting proposals will end on 15<sup>th</sup> April 2021.

## 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 obtain the necessary documentation to prepare their proposals through the contractor's profile on the website [www.isglobal.org](http://www.isglobal.org).

**XIV. PAYMENT METHOD**

Sample analysis will be invoiced after its analysis and once the results have been sent to the Client.

Barcelona, March 26<sup>th</sup>, 2021

A handwritten signature in blue ink, appearing to be 'J. Llop', is written in a cursive style.