**Title: Clinical Trial Manager (CTM)**

**Location: Barcelona Campus Clínic**

**Reports to: ANTICOV Principal Investigator (PI) / Chief Scientific Officer (CSO)**

The CTM will work closely with the Project Manager and the Financial Manager who are respectively responsible for the overall project tracking and budgets/accounting.

**Title: Clinical Trial Manager (CTM)**

**Description:**

The Barcelona Institute for Global Health (ISGlobal) is a cutting-edge institute addressing global public health challenges through research, translation into policy and education. ISGlobal has a broad portfolio in communicable and non-communicable diseases including environmental and climate determinants, and applies a multidisciplinary scientific approach ranging from the molecular to the population level. Research is organized in three main areas, Malaria and other Infectious Diseases, Child and Maternal Health, and Urban Health, Climate & Non-Communicable Diseases. ISGlobal is accredited with the Severo Ochoa distinction, a seal of excellence of the Spanish Science Ministry.

**What We Are Looking for:**

ISGlobal is seeking an experienced **Clinical Trial Manager** who is interested in taking over and managing activities of the clinical trial "An open-label, multicentre, randomised, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild / moderate cases of COVID-19" (ANTICOV). The primary objective is to compare the efficacy of alternative treatment strategies versus control on the risk of progression to severe respiratory disease. ANTICOV is a 18 months study funded by the UNITAID.

**Training and experience/Qualifications:**

- Excellent communication and collaboration skills, experience working in diverse cultures
- *Required:*

At least 5 years of experience across all stages of the clinical trial lifecycle, i.e. from protocol development to final study report. Experience managing clinical trials funded from the commercial and development funding sectors, site development and support trial/s under first-tier regulatory review

- Management of clinical trial teams
- Minimum of BSc or health/science degree equivalent
- Current ICH/GCP certification
- Willingness to travel to site in Africa

- *Preferred:*
  - Previous experience in field trials
  - Previous experience in prevention trials, either drugs or vaccines

## Specific Requirements:

- Results-oriented approach to problem solving
- High professional standards for clinical trial execution, monitoring and reporting
- Accustomed to team work and willingness to contribute to elements outside the clinical trial scope
- Ability to work under pressure
- Ability to work independently where necessary

## Key Responsibilities:

- Ensures that all human subject research activities that will be done under ANTICOV are conducted under standards of Good Clinical Practices/ICH as per ISGlobal's SOPs
- Supports the clinical research teams at headquarters and site levels in the full spectrum of the trial including:

  - Protocol development
  - Obtaining Ethical and regulatory approval for the trial prior to study site initiation
  - Trial management activities from start up to close out
  - Development of trial tools and templates
  - Management of clinical trial monitors
  - Review and approval of monitoring reports
  - Review and approval of monitor timesheets and expenses
  - Site management and closure
  - Trial tracking
  - Verify that all subject research activities undertaken in field sites as part of the ANTICOV project are conducted according to the standards of ICH-Good Clinical Practice, international and local regulations.

- Receives and takes appropriate action following monitoring reports
- Oversees and coordinates study drug supply from procurement to delivery on site, including the required documentation.
- Oversees and coordinates the process for pharmacovigilance/safety of the trial

- Maintains responsibility for the Trial Master File and archiving of thereof, for the correct filing and archiving of clinical trial documents, and the maintenance of study files.
- Coordinates, manages and participates in clinical trial meetings
- Provides project status updates and reports to the PI/CSO as required
- Risk identification and escalation to the PI/CSO
- Issue identification and applicable escalation to the PI/CSO
- Participates in site initiation visits and assists with HSR training of field staff.
- Attends consortium and other meetings as required. Presents data as required.
- Contributes to funder reports

**Specific Duties:**

This position requires international travel, including site visits to Mozambique

**Skills:**

- Teamwork
- Problem resolution
- Learning capacity

**Language level:**

- Excellent written and spoken English
- Working experience in Portuguese/Spanish

**Conditions**:

Duration: One year

Starting date: **As soon as possible**

Contract: full time

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Salary Range: Compensation for this position will be based on the applicant's experience and qualifications.

*During the crisis caused by COVID19, standard working conditions will be adapted to sanitary requirements*.

**How to apply:**

Applicants must fill in the request form and include the following code reference position: **CTM_ANTICOV-ISGLOBAL_Aug20** attach the CV and a Cover Letter. Each attached document must be named with the candidate name and surname.

The receipt of applications will be open until **26th August 2020**.

**Applications will be accepted until 17.00 CET of the closing date.**

**Only shortlisted candidates will be contacted.**

*In ISGlobal we are committed to maintaining and developing a work environment in which the values and principles of our organization are respected and equal opportunities between women and men be promoted in each of the areas in which we operate, not tolerating discrimination based on criteria such as age, sex, marital status, race, ethnicity, disabilities, political leanings, religion or sexual orientation.*