Job Description

Clinical Safety Monitor

ISGlobal (Barcelona, Spain)

The Barcelona Institute for Global Health, ISGlobal, is the fruit of an innovative alliance between academic, government, and philanthropic institutions to contribute to the efforts undertaken by the international community to address the challenges in global health. ISGlobal provides a hub of excellence dedicated to scientific research and the provision of health care. The institute, which originated in a joint initiative of the Hospital Clínic de Barcelona and the University of Barcelona, has amassed over 30 years of experience in the field of global health. The pivotal mechanism of its work model is the transfer of knowledge generated by scientific research to practice, a task undertaken by the Research, Training and Policy and Global Development departments. Its ultimate goal is to help close the gaps in health disparities between and within different regions of the world.

ISGlobal is seeking an experienced **Clinical Safety Monitor** who is interested in working in the research activities of the project **"An efficacy trial of the incremental mortality benefit of IPTi plus azithromycin" (IPTi-plus).** The overall project goal is to contribute to reduce infant mortality in areas of high mortality and malaria burden in Sub-Saharan Africa.

The five-year project, funded by BMGF, the Bill&Melinda Gates Foundation (BMGF) and coordinated by ISGlobal, the Barcelona Institute for Global Health, will evaluate the impact on childhood mortality of azithromycin (AZI) plus intermittent preventive treatment with sulphadoxine-pyrimethamine (IPTi-SP) administered through the Expanded Program on Immunisation (EPI) in Sierra Leone and Mozambique.

The ISGlobal-led consortium includes ISGlobal, as lead research and principal recipient and responsible to BMGF for the implementation of the Project and other local counterparts. The consortium will work closely with the Ministries of Health in Sierra Leone and Mozambique, the World Health Organization (WHO) as well as other stakeholders, to ensure that all project outputs are met.

IPTI-plus will generate evidence for change and expand access to preventive chemotherapy for infants in sub Saharan Africa through the:

1. Evaluation of the impact of azithromycin, plus intermittent preventive treatment with sulphadoxine-pyrimethamine administered through the Expanded Program on Immunisation on all-cause mortality in young children living in areas of high mortality and malaria burden in Sub-Saharan Africa.
2.Evaluation of the Expanded Program on Immunisation (EPI) as a delivery channel to ensure the long-term sustainability of interventions targeted to young children, and specifically IPTi, a safe, efficacious and cost-effective intervention recommended by WHO.

ITPi-plus will apply a community-based approach that fosters partnership and strengthens the dynamic link between communities and health facilities, especially for the most vulnerable people. A learning-driven approach will be employed throughout the project to generate sufficient evidence to inform WHO policy recommendations and future actions in each country, in an effort to expand the intervention over the long-term.

ISGlobal is the lead evaluation and research organization and is responsible for implementing a set of studies to generate evidence for global guidance on IPTi-plus. Specifically, ISGlobal will be responsible for designing and implementing the project's evaluation plan, as well as designing, analyzing and reporting the clinical and operational research studies to assess the efficacy and impact of the intervention (IPTi-plus), including an **individually randomised**

placebo-controlled trial in infants exposed to malaria and high mortality burden, and the feasibility of the intervention (IPTi) through the EPI.

In order to ensure the successful implementation and quality of the trial, ISGlobal is seeking a Safety Monitor.

RESPONSIBILITIES:

- Ensure timely and quality monitoring of the safety signs of study drugs and achievement of the established objectives
- Ensure efficient implementation of the safety monitoring procedures
- Responsible for the implementation of the Safety Monitoring Plan
- Responsible for communication with the Project coordination team and the site's principal investigators (PIs) according to the project's Standard Operation Procedures (SOPs)

Under the guidance of the Project Director (PD) and the Technical coordinator (TC) the candidate will be expected to undertake the following:

DUTIES:

- Prepare the Safety Monitoring Plan in coordination with the Project Technical coordinator
- Ensure that all safety monitoring procedures are implemented according to project objectives and timelines
- Work closely with the Project team and the PIs for ensuring standardization of safety monitoring procedures
- Review the Severe Adverse Events (SAEs) according to the notification system in place at ISGlobal and its coordination with sites
- Reception and management of SAEs forms at ISGlobal: responsible for evaluating SAEs in terms of clinical and severity significance and notifying the trial Data Safety Monitoring Board (DSMB)
- Responsible for communicating with trial investigators on-site if a SAE requires an immediate action
- Responsible for keeping updated the SAEs database at ISGlobal and working closely with ISGlobal Statistician in DSMB periodic reports
- Monitoring the clinical trial safety signs throughout its duration
- Write safety monitoring reports periodically and of field trips to the Technical Coordinator
- Preparing and keeping updated the safety monitoring trial file
- Ensuring fluid coordination and communication with the IPTI-plus Project Manager
- Ensuring an efficient relationship with the investigator's team
- Travel on a regular basis to project countries (Sierra Leone, Mozambique) to implement and supervise the clinical trial activities of the project
- Conduct and supervise the training in the project countries
- Interact with local counterparts' implementing team in the project countries

COMPETENCES:

Qualifications:

- University degree in Medicine
- Experience in clinical trials and advanced knowledge of GCP and legislation about clinical trials will be a strong plus

Required competencies:

- Excellent management, project planning, and organizational skills
- Knowledge of written and spoken English is required; knowledge of Spanish, Catalan, Portuguese are a strong plus
- Excellent computer skills: MS Word, Excel, Outlook software or equivalent
- Ability to effectively work both as a team member and independently
- Experience working in international environments is preferred, experience in developing countries and in malaria research will be a strong plus
- Full-time schedule and exclusive dedication
- Oriented to train and transfer knowledge to biomedical staff in African contexts.
- Excellent writing ability to elaborate high-quality and concise technical reports.

Desirable:

- Ability to adapt to new environments, work effectively as part of the team and use own initiative when required
- Flexibility. Open to new ideas and new working methods, adapt positively to change, exchange views and opinions with colleagues.
- Ability to design and develop activities, to achieve milestones and specific deliverables, and to meet deadlines
- Effective written and verbal communication skills
- To have a genuine interest in biomedical research of infectious diseases, capacity building and global development

We offer:

- Full-time position, office-based in Barcelona
- Fixed-term contract for all project length (up to 60 months), starting in June 2019
- Salary according to the applicant's experience and qualifications and project budget.

HOW TO APPLY:

Applicants must fill in the request form and attached the relevant documents including the following reference: **CSM_IPTI-Plus_ June19**. Each document must include the candidate name and surname.

fact The receipt of applications will be open until **June, 23nd 2019.**

Applications should also include the names and email contacts of 2 referees who can be contacted immediately if shortlisted

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