

Job description – Clinical Trial Manager

Job code:	17022301	Location:	Ho Chi Minh City, may require frequent domestic travel to research sites
Job category:	Clinical Trials	Regional office:	HCMC
Job level:	Manager	Direct report:	Country Manager, Principal Investigator
Type of work:	Full-time	Dotted-line reporting:	
Duration:	1 year with the possibility of subsequent extension	Tentative start date:	March 2023

Main roles: To coordinate the implementation of a TB clinical trial. The role includes:

- Taking a leading role in planning, executing, monitoring and closing the trial,
- Overseeing quality assurance and safety for the clinical trial, in keeping with international standards of Good Clinical Practice,
- Building a team of enthusiastic and capable research staff.

Management and report:

Country Manager and Principal Investigator for trials.

Direct line supervisor for:

Key staff working with the project:

- Project Officers
- Data Manager
- Local financial controller
- Senior field staff
- Technical managers (such as Laboratory staff)

Duties and Responsibilities:

- Develop and strengthen key relationships with government partners
- Planning and executing the trial



- Prepare protocol and trial documents for registration according to requirements of sponsors and authorities
 - Developing and implementing pilot projects to test key components of the trial
 - Development and evaluation of trial-related materials including the Standard Operating Procedures, trial documentation and forms, and trial marketing (promotion) materials
 - Obtaining and maintaining facilities, equipment and licences as required for implementing the trial (including drug procurement)
 - Training field research teams and government health staff to implement the SOPs (including informed consent, safety, and compliance issues)
 - Develop and update project log frame regularly.
- Co-ordination and monitoring of the clinical trial
 - Oversee patient recruitment
 - Monitoring of the implementation of the trial including subject recruitment and implementation of all study procedures
 - Reviewing study protocols, progress reports, and interim results to ensure that studies are being conducted according to design and that results are accurately recorded
 - Coordinating with investigators to ensure that all research activities are carried out in accordance with protocols and approved by ethics boards
 - Ensuring timely and accurate data collection and completion of case report forms relevant to clinical trials or research projects, and maintaining the Trial Master File (TMF) to GCP standards
 - Registration and management of adverse events
 - Managing monitoring visits and dealing with queries
 - Arrange meetings, teleconferences, and video conferences relating to the project
- Preparing and sending correspondence to investigators and sponsors regarding study procedures and requirements
- Financial Accountability
 - Preparing budgets and managing budgets for clinical trials
 - Ensure efficient expenditure of resources.
 - Ensuring appropriate financial control processes are followed.
- Human resource management accountability
 - Recruit local staff to conduct the research.
 - Supervise performance of all staff.
 - Foster a community of learning and teamwork, continuous quality improvement and continuous professional development for staff
- Close-out of the trial
 - Trial closure
 - Communication with organisations involved.

- Assisting in preparation of the final study report
 - Oversee completion of financial reporting.
- Notifying Country Director and Chief Investigators about problems arising in the study

Key attributes

- ability to work within a team and organise it
- management skills
- strategic planning
- ability to prioritise
- a motivator with good listening skills
- focused, but flexible approach
- willingness to work hard
- knowledge/experience of all relevant guidance/regulations
- ability to pay close attention to details

Qualifications

- Required formal qualification in trials management, clinical trials management, international development, or a field of study related to the scope of the position.

Essential criteria

- Excellent team leadership skills
- Strong organizational management skills
- Experience working in a cross-cultural context and in a developing country setting (preferably Vietnam, but this is not essential)
- Skills in institutional capacity-building
- Experience in engaging with government and non-government partners
- Proven experience in negotiation and managing conflict
- Fluency in English and excellent communication skills
- Ability to communicate fluently in Vietnamese