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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

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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

Applications:

For interested applicants, please send a cover letter together with a CV (with the name and contact details of at least three senior referees) in English or Vietnamese and scanned copies of your related degrees, no later than 10/03/2023 by submitting the application form in the link as follows: http://bit.ly/woolcockhiring

We regret that only short-listed candidates will be contacted for interviews. Review of applications will start as soon as possible and continue until 10/03/2023, or until the post is filled, whichever is earlier.