

## Job description - Senior Trial Officer - VQUIN Study

**Organisation:** Woolcock Institute of Medical Research in Vietnam

The Woolcock Institute is lung health research organisation, based at Sydney University, Australia (<http://www.woolcock.org.au/>). The Institute has operated in Vietnam since 2009, we undertake large and important operational and epidemiological and clinical research projects in collaboration with the National Tuberculosis Program in 9 Provinces, including Ha Noi and Ho Chi Minh City. The Woolcock also runs training in epidemiological and operational research methods for Vietnamese doctors and public health workers. Currently the Woolcock directly employs 70 full-time staff across the Vietnam..

**Location:** Based in Ha Noi

**Duration:** 12 months appointment, with consideration for subsequent extension.

### Roles:

- To lead the implementation of VQUIN in 4 Provinces of Vietnam in the Northern area including: Nam Dinh, Quang Nam, Da Nang, Thanh Hoa. The role includes:
  - Taking a leading role in planning, executing, monitoring and controlling the trial
  - Overseeing quality assurance and safety for the clinical trial, in keeping with international standards of Good Clinical Practice
  - Perform assigned key tasks in Ha Noi
- Building a team of enthusiastic and capable research staff in 4 Provinces delegated

**Direct report:** VQUIN Trial Manager

### Duties and Responsibilities

1. Direct line supervisor for: all Trial Officers in 4 Provinces in charge for all key activities as follows:

- Develop and strengthen key relationships with collaborative partners in assigned areas
- Planning and executing the trial
  - Implementing pilot projects to test key components of the trial
  - Assembling and training a team to oversee the trial
  - Assisting in the evaluation of trial-related materials including the Standard Operating Procedures, trial documentation and forms, and trial marketing (promotion) materials
  - Overseeing preparation and submission of routine regulatory and ethical review submissions and reports within delegated authority and areas
  - Maintaining facilities and equipment 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)
  - Being the primary point of contact between Woolcock, the investigators, and the research sites in delegated Provinces for the implementation of the research
  - Trial recruitment and case-management (approximately 2 days/week, based in Ha Noi Lung Hospital)
    - Recruiting study subjects (including patients with TB and their household contacts)
    - Scheduling appointments for the follow-up of study subjects
    - Conducting assessments of study subjects during routine follow-up visits
    - Referring subjects for medical assessment according to protocols
    - Arranging routine diagnostic testing of subjects
    - Support local health care workers in recruitment, clinical assessment and reporting (including Provincial Hospital and District Clinic staff)

### Vietnam Country Office:

- ♦ No 203, 2G Building, 298 Kim Ma street  
Van Phuc Diplomatic Compound, Ba Dinh, Hanoi
- ♦ Tel: (84 - 24) 3762 1938
- ♦ Website: <http://www.woolcockvietnam.org/>

- Co-ordination and monitoring of the clinical trial
  - Monitoring of the implementation of the trial including subject recruitment and implementation of all study procedures
  - Data collection and management
  - Monitoring data quality
  - Collection and archiving of source documents
  - Assisting in report of adverse events
  - Managing monitoring visits and dealing with queries
  - Preparing reports for the Trial Coordinator on progress of trial implementation
- Communication with Trial Coordinator, Country Director, WIMR management, and the Chief Investigators
  - Coordination of visits by Chief Investigators and Trial Coordinator
  - Preparing project progress reports to Trial Coordinator and other partners when required
- Financial accountability
  - Fulfilling financial responsibilities delegated according to VQUIN financial procedures
  - Establishing effective procurement control and asset management in delegated study areas
  - Assisting in oversight of budget, audit and financial accounting in delegated study areas
  - Ensure efficient expenditure of resources
  - Ensuring appropriate financial control processes are followed
- Human resource management accountability
  - Assist in recruiting local staff to conduct the research in delegated study areas
  - Supervise performance of all staff under delegated authority
  - Foster a community of learning and teamwork, continuous quality improvement and continuous professional development for staff
- Close-out of the trial
  - Assisting in communication with organisations involved within delegated study areas
  - Assisting in preparation of the final study report

## 2. Key tasks in Ha Noi:

- Finance work
  - Support assigned provinces in preparing financial submissions to the National Lung Hospital (NLH)
  - Collect quarterly financial reports from participating provinces
  - Assist the Financial department to complete the quarterly financial reports for all provinces
- Administrative tasks
  - Support in obtaining necessary licenses/approvals for study-related purchases for implementing the trial
  - Support the preparation of reports, official letters that need to be issued by the NLH for the project (obtain Dr Nhung's signature and send to provinces)
  - Support in study drug management and distribution
  - Translation/interpretation
  - Support in maintaining updated approval documents for the study provided by the NLH, Ministry of Health and other Vietnamese government bodies and central study regulatory binders (trial master file)
  - Other tasks as required.
- Notifying Trial Coordinator, Country Director and Chief Investigators about problems arising in the study
- Foster a community of learning and teamwork, continuous quality improvement and continuous professional development for staff

## Required education, skills and qualities:

- Degree in Science, Pharmacy, Medicine, Nursing, Public Health or related field.
- Experience in conduct, coordinating, monitoring or quality assuring of clinical research

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- Proven oral and written presentation skills.
- Excellent diplomatic communication and interpersonal skills.
- High level of organizational and record keeping skills.
- Excellent Vietnamese and English language skills.
- Scientific and/or clinical knowledge needed to monitor the trial adequately
- Understanding of ICH-GCP guidelines, local and international regulations on clinical research.
- Self-starter, detail-oriented, good time management, problem solver, flexible and adaptable, self-confident
- Willing to travel within Viet Nam

### **Application Procedure**

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 **20 November 2019** by submitting the application form in the link as follows:

<https://airtable.com/shrEHhrmyayGTWOjs>

Review of applications will start as soon as possible and continue until **20 November 2019**, or until the post is filled, whichever is earlier. We regret that only short-listed candidates will be contacted for interviews.

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