

Job description – Trial Officer, VQUIN Study

Organisation: Woolcock Institute of Medical Research

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 11 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. We are recruiting a highly motivated and experienced Senior Study Officer to participate in the pilot and implementation of the VRESIST study, which aim to prevent the antimicrobial resistance in Vietnam.

Location: An Giang

Duration: 06 months appointment, with consideration for subsequent extension. This position will be on full time basis.

Roles:

- To support establishing, executing and monitoring the trial
- To ensure the compliance with international standards of Good Clinical Practice

Direct report:

Southern Area Leader/Trial Coordinator, Woolcock Institute of Medical Research

Key staff working with the project:

- Trial Officers
- Local health workers
- Local financial controller
- Technical managers (such as Laboratory staff)

Duties and Responsibilities

To work with research and clinical team to implement PK and microbiome components in clinical trial including but not limited to contributing to contract negotiation, finalizing SOP, CRFs, coordinating study activities at all responsible sites from startup to closeout, and working with other Trial Officers in recruitment and case management.

Trial recruitment and case-management

- Recruiting study subjects
- 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
- Supporting local health care workers in recruitment, clinical assessment and reporting (including Provincial Hospital and District Clinic staff)

Training and oversight

- Providing support for training of local health staff
- Organising and facilitate training workshops within the Province
- Understanding relevant clinical research protocols and regulatory requirements.

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/>

- Training local partners in protocol relevant procedures including those for laboratory samples, data collection and recording, medication and patient assessment

Team collaboration

- Working closely with the Trial Coordinator and Chief Investigators
- Notifying Country Director and Chief Investigators about problems arising in the study

Logistical support

- Organize logistics of study materials including drugs, files, test kits, patient samples, data and other materials.
- Purchase study materials when required

Data collection and administration

- Plan, implement and coordinate all aspects of data collection, recording and source documentation, as per hospital and Woolcock policy and ICH GCP guidelines.
- Execute study-related administrative tasks, such as collection of data and regulatory documents, managing reimbursement for patients and study staff, filing or retrieving files, maintaining patient charts and supply inventories, etc.
- Verify that data entered on to CRFs is complete and consistent with patient clinical notes, known as source data/document verification.
- Coordinate patient visit schedules as per study protocol

Good clinical practice compliance

- Supervise the conduct of the study to ensure compliance with the principles of Good Clinical Practice, which will involve visiting the study sites on a regular basis.
- Track study progress and identify problems. Report to stakeholders as required

Support study monitoring

- Liaise with sponsor for monitoring/audits. Write, file and collate trial documentation and visit reports with respect to monitoring.
- Participate in study team meetings to share experience and contribute to the knowledge of others in the team

Other tasks

- Attend career training to improve skills and update relevant knowledge.
- Other tasks as required

Key attributes:

- University degree in Medicine, Nursing, Pharmacy, Science, Public Health or related field
- Experience in laboratory (preferred)
- Experience in implementation of clinical trials in Vietnam
- Ability to work as a member of a team, and collaborate closely with government health staff
- High level of organizational and record keeping skills
- Knowledge of ICH GCP guidelines
- An ability to work independently
- Ability to communicate fluently in Vietnamese

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 **30/11/2021** by submitting the application form in the link as follows:

<https://airtable.com/shrEHhrmyayGTWOjs>

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We regret that only short-listed candidates will be contacted for interviews.

Review of applications will start as soon as possible and continue until 30/11/2021, or until the post is filled, whichever is earlier.

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