

Job description – Trial Officer – VSMART Study

Organisation: Woolcock Institute of Medical Research

The Woolcock Institute of Medical Research is affiliated with the University of Sydney in Australia and is recognized as one of the leading research institutions for respiratory diseases and sleep disorders. Operating in Vietnam since 2009, we have undertaken large operational, epidemiological and clinical research projects and run training in epidemiological and operational research methods for Vietnamese doctors and public health workers. The Woolcock Institute has three research centres and offices in Ha Noi, Ho Chi Minh City and Ca Mau. Currently we directly employ about 50 full-time staff and coordinates multiple study projects within lung health management and treatment across eleven provinces. We also expand research activity to other fields including antimicrobial resistance.

For more information about us, please visit:

Woolcock Institute of Medical Research in Sydney, Australia: <http://www.woolcock.org.au/>

Woolcock Institute of Medical Research in Vietnam: <http://www.woolcockvietnam.org/>

Overview: The V-SMART Trial is a randomised controlled trial of an mHealth intervention (“Bác Sĩ Minh” mobile and web-based application) to improve treatment outcomes for patients with multidrug resistant tuberculosis (MDR-TB). Patients and health workers will be linked using new digital technologies, enabling greater continuity of care and improving patient safety and treatment outcomes. These technologies will allow local health workers and TB programmes to monitor the management of adverse events, support patient adherence and respond rapidly to adverse events before they cause disability.

The trial will be conducted within the National TB Program in seven provinces of Vietnam. The project will enhance local capacity in mHealth research and demonstrate the transformative potential of new technologies for both patients and health systems.

Work location: Ho Chi Minh city, Hanoi, An Giang and with possibility of domestic travel

Number of staff to be recruited: 4 staff: 1 in Hanoi, 2 in HCMC, and 1 in An Giang

Duration: 12 months appointment, with consideration for subsequent extension. This position will be on full time basis.

Direct report:

- Study Manager of VSMART Study

Key staff working with the project:

- Trial Officers
- Local health workers
- Local financial controller
- NTP Coordinator

Roles:

- To establish, implement and monitor the trial
- To ensure the compliance with Good Clinical Practice standards

Duties and Responsibilities:

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/>

To work with study manager and local stakeholders to implement V-SMART, including but not limited to, contributing to contract negotiation, finalizing Standard Operating Procedures (SOP), completing case report forms (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

- Screening potential subjects, transfer to study doctors for consultation and follow-up on subjects' consent to participate
- Interviewing consented subjects and abstracting clinical records for baseline data collection
- Installing study app to subjects' smartphones and introducing app functions to the subjects
- Managing and recording site recruitment logbook in a weekly basis

Case management

- Communicating with intervention subjects on their app use and experience of adverse events every fortnight
- Reminding healthcare workers on responding to patients' request via the app and recording their actions of response
- Reminding healthcare workers on updating patients' laboratory test results as required in the app
- Follow-up on healthcare workers' investigation of adverse events and reporting SAEs to the National DI&ADR Centre and the Study
- Conducting follow-up of study subjects via telephonic interviews every 3 months

Training and oversight

- Contributing to development of study SOPs
- Providing support for training of local health staff
- Organising and facilitate training and monitoring workshops within the Province
- Training local partners in protocol relevant procedures including those for data collection and recording, app use and reporting via app, and adverse event management

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
- Organize logistics of study materials including site investigator file, patient files and other materials. Comply with study regulations on filing or retrieving files, storing data securely, and inventories, etc.
- Ensure that data entered on to CRFs are complete and consistent with patient clinical notes, known as source data/document verification

Support study monitoring

- Track study progress and identify problems. Report to stakeholders as required
- 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

Team collaboration

- Working closely with the Study Manager and Chief Investigators

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- Notifying Study Manager about problems arising in the study

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.
- Understanding relevant clinical research protocols and regulatory requirements

Other tasks:

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

Essential criteria:

- University degree in Medicine, Nursing, Pharmacy, Science, Public Health or related field
- 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
- Attention to details
- Ability to communicate fluently in Vietnamese, basic English skills is preferred

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 (both CV and cover letter), no later than **31/12/2021** 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 **31/12/2021**, or until the post is filled, whichever is earlier

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