Job description – Senior Trial Officer

Job code:	13012301	**Location:**	Ho Chi Minh City, may require domestic travel to research sites
Job category:	Clinical Trials	**Regional office:**	HCMC
Job level:	Senior Officer	**Direct report:**	Trial Coordinator/Area Leader
Type of work:	Full-time	**Dotted-line reporting:**	
Duration:	12 months with possibility of subsequent extension	**Tentative start date:**	February 2023

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 70 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: www.woolcock.org.au
Woolcock Institute of Medical Research in Vietnam: www.woolcockvietnam.org

Duties and Responsibilities:

- To work with research and clinical team to implement study 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.
- Working with the international Coordinating Centre to address issues relating to data quality, protocol implementation, reporting and monitoring.
- Assist in performing site qualification, site initiation, interim monitoring, site management and close-out **visits (performed on-site or remotely) to ensure regulatory, ICH-GCP and protocol compliance. Uses** judgment and experience to evaluate overall performance of site and site staff and to provide recommendations regarding site-specific actions; immediately communicates/escalates serious issues to the project team and develops action plans. Maintains a working knowledge of ICH/GCP Guidelines or other applicable guidance, relevant regulations, and study SOPs/processes.
- Perform investigational product (IP) inventory, reconciliation and reviews storage and security. Verifies the IP has been dispensed and administered to subjects/patients according to the protocol. Verifies issues

or risks associated with blinded or randomized information related to IP. Applies knowledge of GCP/local regulations and organizational procedures to ensure IP is appropriately (re)labelled, imported and released/returned.

- Routinely reviews the Investigator Site File (ISF) for accuracy, timeliness and completeness. Reconciles contents of the ISF with the Trial Master File (TMF). Ensures the investigator/physician site is aware of the requirement of archiving essential documents in accordance with local guidelines and regulations.
- Documents activities via confirmation letters, follow-up letters, site visit reports, communication logs, and other required project documents as per SOPs and Clinical Monitoring Plan/Site Management Plan, and requirements of study sponsor/funder/investigator(s). Supports subject/patient recruitment, retention and awareness strategies. Enters data into tracking systems as required to track all observations, ongoing status and assigned action items to resolution.
- Prepares for and attends Investigator Meetings and/or sponsor face to face meetings. Attends clinical training sessions according to the project specific requirements.
- Provide training to more junior level study staff. May perform training and sign off visits for junior study staff, as assigned.
- May be mentored and assigned clinical operations lead tasks under supervision of Area Leader/Trial Coordinator.
- Per the Clinical Monitoring/Site Management Plan (CMP/SMP), assist Internal Monitor in:
  - Assessing site processes;
  - Conducting Source Document Review of appropriate site source documents and medical records;
  - Verifies the process of obtaining informed consent has been adequately performed and documented for each subject/patient as required/appropriate;
  - Verifying required clinical data entered in the case report form (CRF) is accurate and complete via review of site source documents and medical records;
  - Applying query resolution techniques remotely and on site, and provides guidance to site staff as necessary, driving query resolution to closure within agreed timelines;
  - Utilizing available hardware and software to support the effective conduct of the clinical study data review and capture;
  - Verifying site compliance with electronic data capture requirements.
- Translate study documents (Vietnamese - English – Vietnamese)
- Support in organizing logistics of study materials including drugs, files, test kits, patient samples, data and other materials.
- Purchase study materials when required.
- Other tasks as required.

Key attributes:

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

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 1/31/2023 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 1/31/2023, or until the post is filled, whichever is earlier