MedResNet

JOB DESCRIPTION
Title of the Position: Clinical Research Associate
Department: Clinical Operation
Direct report: Clinical Operation Manager

Job Purposes:

- The rights and well-being of human subjects are protected.
- The reported trial data are accurate, complete, and verifiable from source documents.
- The conduct of the trial is in comply with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

Key areas of Responsibility:

- Acting as the main line of communication between the project team and investigator.
- Verifying that the investigator has adequate qualifications and resources and remain adequate throughout the trial period, facilities, including laboratories, equipment, and staff, is adequate to safely and properly conduct the trial and remain adequate throughout the trial period.
- Investigational product(s): That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.
- That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
- That the subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s). That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.
- That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.
- Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.
- Verifying that written informed consent was obtained before each subject's participation in the trial.
- Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).
- Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.
- Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution and have not delegated these functions to unauthorized/unqualified individuals.
- Verifying that the investigator is enrolling only eligible subjects.
- Reporting the subject recruitment rate.
- Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained.
- Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.
- Checking the accuracy and completeness of the case report forms (CRF) entries, source documents and other trial-related records against each other. The CRA specifically should verify that:
    - The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents.
    - Any dose and/or therapy modifications are well documented for each of the trial subjects.
    - Adverse events, concomitant medications and intercurrent illnesses are reported in accordance with the protocol on the CRFs.
    - Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs.
    - All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRFs. Informing the investigator of any CRF entry error, omission, or illegibility. The CRA should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialed by the investigator or by a member of the investigator's trial staff who is

authorized to initial CRF changes for the investigator. This authorization should be documented.
- Determining whether all adverse events (AEs) are appropriately reported within the time periods required by Good Clinical Practices (GCP), the protocol, the Ethic Committees (IRB/IEC), the sponsor, and the applicable regulatory requirement(s).
- Determining whether the investigator is maintaining the essential documents.
- Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

Qualification, Knowledge, Skills, and Abilities

- A Bachelor's degree in a health care or other scientific discipline or educational equivalent
- Must be willing to travel for at least 5 to 10 days in a month, though not necessarily continuous.
- Computer skills including use of a laptop computer, knowledge of Microsoft Word, Excel and PowerPoint preferred.
- Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical research and data management methods. Strong written and verbal communication skills including good command of English required.
- Excellent organizational and problem-solving skills.
- Effective time management skills and ability to manage competing priorities.
- Ability to establish and maintain effective working relationships with co-workers, managers and clients

Additional information

- **Experience:** 0-3 year(s) of onsite monitoring experience
- **Location:** office based, Bangkok

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