

Taiwan Jobs Expertini®

Senior Clinical Research Associate

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Company: Everest Clinical Research Services Inc

Location: Taiwan

Category: other-general

Everest Clinical Research (“Everest”) is a full-service contract research organization (CRO) providing a broad range of expertise-based clinical research services to worldwide pharmaceutical, biotechnology, and medical device industries. We serve some of the best-known companies and work with many of the most advanced drugs, biologics, and medical devices in development today.

Everest has been an independent CRO since 2004 with a strong foundation as a statistical and data management center of excellence. Building on this foundation, Everest has successfully developed and established itself as a full-service CRO. Everest’s headquarters are located in Markham (Greater Toronto Area), Ontario, Canada with additional sites in Bridgewater (Greater New York City Area), New Jersey, USA, Shanghai (Pudong Zhangjiang New District), China and Taipei, Taiwan.

Everest is known in the industry for its high quality deliverables, superior customer service, and flexibility in meeting clients’ needs. A dynamic organization with an entrepreneurial origin, Everest continues to experience exceptional growth and great success.

Quality is our backbone, customer-focus is our tradition, flexibility is our strength...that’s us...that’s Everest.

To drive continued success in this exciting clinical research field, we are seeking committed, skilled, and customer-focused individuals to join our winning team as **Senior Clinical Research Associates**.

Key Accountabilities:

Interact with personnel from study Sponsors, investigational sites, vendors, and Everest

functional groups to enable quality and on-time execution of clinical trials in compliance with ICH-GCP and relevant local regulations.

Identify potential sites for participation in clinical trials.

Perform protocol/site feasibility and Pre-Study Visits to recommend qualified sites.

Participate in Investigator Meetings, Clinical Research Associate (CRA) and Study Coordinator training sessions, and assist sites with study-related questions as needed.

Provide feedback to study manuals, Case Report Form completion guidelines, monitoring plans, informed consents, recruitment materials, and monitoring tools, as needed.

Perform Site Initiation Visits, Interim Monitoring Visits, and Close-Out Visits in compliance with the approved protocol and monitoring plan.

Submit quality and on-time Monitoring Visit Reports and follow-up letters to the Clinical Operations Lead or designee for review and approval via Clinical Trial Management System (CTMS).

Complete monitoring visit reports and follow-up letters, including summaries of the significant findings, deviations, deficiencies, and recommended actions to ensure site compliance.

Assist with oversight visits and monitoring visit report review/approval of CRA I/II, evaluating their performance and providing feedback to their supervisor, if requested.

Review ISFs to ensure essential documents are current and submitted to the TMF throughout the trial for reconciliation purposes. Ensure sites have submitted relevant documents to their Institutional Review Board/Ethics Committee as needed. The CRA is responsible for ensuring that the TMF is maintained in an inspection-ready state.

Establish regular lines of communication and administer ongoing protocol/study-related training to assigned sites.

Assist with site management tasks and ensure continuous data flow (i.e., on-time site data entry, query resolution, and source document verification). Assess the clinical research site's patient recruitment/retention success and offer suggestions for improvement.

Ensure proper handling, accountability, and reconciliation of all investigational products, medical

devices, and clinical trial supplies.

Prepare sites for inspections/audits conducted either by regulatory authorities, Sponsors, or Contract Research Organizations.

Submit accurate and on-time expense reports.

Assist with preparation of materials for Requests for Proposals and bid defenses.

Assist the Clinical Operations team with additional related tasks as needed.

Plan and carry out professional development.

Complete timesheets as requested and on-time.

Qualifications and Experience:

Bachelor's degree in a Life Science or related field of study.

Minimum of 4 years' of relevant and/or monitoring experience.

Thorough knowledge of ICH-GCP guidelines and applicable regulations.

Thorough comprehension of medical terminology.

Excellent organization and communication skills (both verbal and written).

Ability to travel a maximum of 70% of working hours to locations nationwide. Less travel hours may apply for projects with remote/virtual visits.

Must maintain a valid driver's license and be able to drive to monitor sites.

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