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Senior Clinical Database Designer

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Company: Everest Clinical Research Services Inc

Location: Taiwan

Category: other-general

Brightech is a leading CRO that specializes in complex, value-add biostatistics, programming, and clinical data management services. Brightech, an Everest Clinical Research Company, has earned a highly-regarded reputation as a critical partner for some of the world's largest pharmaceutical and biotech companies.

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 a **Senior Clinical Database Designer** for our Taipei, Taiwan on-site location.

Key Accountabilities:

Design clinical database for new studies based on requirement specifications in various electronic data capture (EDC) systems. Design includes, but not limited to, case report forms (CRF), edit checks, study roles, laboratory, coder, RTSM.

Perform post go-live changes (database modifications) based on updated requirement specifications in various electronic data capture (EDC) systems, provide impact assessment for modifications.

Perform Unit Testing on database design, assist User Acceptance Test (UAT) activities, address UAT findings.

Setup and configure the development environment for new studies.

Assist the creation of the Database Integration Specification (DIS) with other systems, provide Integration Technical Detail (ITD) as needed, program the integration and assist the integration test.

Support Data Manager (DM) in investigating and addressing issues related to the database design.

Assist study decommission and archiving.

Develop new features and functionality within the database design functional areas to increase the efficiency of database design at the study level and to improve and enhance the company’s database design capabilities.

Review study design requirement specifications, ensuring the specifications adhere to EDC platform standards and Everest Standards with best design practice. Specification includes, but not limited to, CRF and Visit Map specification, Data Validation Specification (DVS), Role Configuration Specification (RCS)

Review the protocol and associated reference material, ensuring study design specifications meet the protocol requirement, and contribute to the development of the database design project timeline. Maintain database design timelines and promote good project management

practices.

Assist Clinical Data Management in planning, directing, and managing the clinical database design and maintenance process.

Follow up on regulatory requirements, industry trends, benchmarking, and best working practices in data management and database design by reading, participating in relevant training, and/or relevant association activities.

Participate in EDC vendor's technical learning and exchange meetings, as well as other internal and external training meetings.

Contribute to the development and maintenance of the company's database design procedural documents, work instructions, checklists, and templates for all EDC systems.

Provide input to all database design-related data management procedural documents.

Cooperate with and assist the Quality Assurance department with quality control audits on assigned databases. Validate and disseminate real-time study monitoring reports to Sponsor and internal team members.

Participate in and contributes to Clinical Data Management initiatives.

Qualification:

B.Sc. in Biological Sciences or Computer Science.

Five years' related experience.

Two to three years developing Inform, iDatafax/DFdiscover, Clinical One and/or Medidata Rave (or similar) clinical databases.

Must communicate effectively, orally and in writing, with personnel on all professional and administrative levels.

Proven leadership and interpersonal skills in complex team situations.

Excellent presentation skills and the ability to build relationships with both internal and external clients.

Must be well-organized, able to work independently, and manage multiple projects/tasks

appropriately.

Demonstrated ability to effectively organize and integrate the activities of information processing personnel.

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