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Senior Statistical Programmer

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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 also recently completed the acquisition of August Research. August Research is a European CRO that provides Clinical Operations and Pharmacovigilance services to a wide variety of pharmaceutical and biotechnology clients. The Company has worked on over 120 projects for Phase I-IV clinical trials across multiple therapeutic areas including cardiovascular, infectious disease, oncology and rare disease. The acquisition of August Research establishes a European footprint for Everest to provide full-service offerings to its pharmaceutical, biotechnology and medical devices clients, and other operational capabilities through the Company’s substantive experience and infrastructure across 14 countries in Western and Eastern Europe.

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 Statistical Programmers** for our Brightech location in **Taipei, Taiwan** with opportunities to work remotely in accordance with our Work from Home policy.

Key Accountabilities:

Lead efforts in resolving day-to-day work-related issues and problems, ensuring quality of deliverables, as well as improving the efficiency and productivity of statistical programming work.

Lead assigned projects by applying project management skills and statistical programming techniques; achieve on-time delivery of deliverables with quality, as well as earn client's trust and repeat business.

Develop SDTM and ADaM dataset specifications for CSRs, ISS, and ISE following company's or client's Standard Operating Procedures (SOPs) and project specific requirements. Perform quality control (QC) review of these documents prepared by others.

Program and validate SDTM and ADaM datasets following approved dataset specifications for CSRs, ISS, and ISE.

Perform CDISC standard compliant checks on SDTM and ADaM datasets. Generate, review, and resolve Pinnacle 21 validation issues. Perform additional QC checks on these deliverables using company Working Instruction (WI) QC checklists.

Perform overall quality/consistency review of statistical TLGs before delivering them to the internal team or the client.

Create SDTM and ADaM define.xml files. Perform QC review of these files prepared by others.

Participate and/or lead programming teams in support of product regulatory submission related activities.

Learn and maintain expertise in the use of the utilities and macros developed for the Statistical Programmers. Develop new macros and utilities.

Program and perform QC/validation of complex data integrity checks to ensure data quality and ongoing scientific data surveillance.

Complete job-required and project-specific training. Comply with applicable Everest and trial Sponsor's Policies, SOPs, and WIs.

Document data and programming information in accordance with corporate SOPs and guidelines.

Archive clinical trial data (SDTM and ADaM datasets) and programming information in accordance with corporate archival SOPs and guidelines.

Qualifications:

A Master's or Ph.D. degree in Statistics, Biostatistics, Epidemiology, and Computer Sciences, with at least four years' experience in clinical trial statistical programming

OR

A Bachelor's degree in the above fields with at least six years' experience in clinical trial statistical programming.

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