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Statistical Programmer I

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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 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 a **Statistical Programmer** for our Brightech location in **Taipei, Taiwan** , with opportunities to work remotely from a home-based office in accordance with our Work from Home policy.

Key Accountabilities:

Statistical Programming:

Under supervision, may develop and review SDTM and ADaM dataset specifications, annotated Case Report Forms (CRF) and other related documents (e.g., define.xml, reviewer's guide) based on Statistical Analysis Plan (SAP), Everest company Standard Operating Procedures (SOPs) and Working Instructions (WIs), industry data standards, regulatory requirements, and trial Sponsor-specific requirements.

Program and validate SDTM and ADaM datasets following approved dataset specifications; perform CDISC conformance checks on generated SDTM and ADaM datasets and address conformance findings.

Develop SAS programs to generate and validate statistical output reports of trial data based on the SAP and TLGs mock-up shells.

Provide statistical programming support to Clinical Study Reports, clinical trial efficacy and safety data integrations (Integrated Summary of Safety and Integrated Summary of Efficacy), as well as other data analysis and reporting needs such as regulatory required safety reports (e.g. Development Safety Update Report, 120 Day Safety Update, etc.), ad-hoc requests, and exploratory data analyses.

Clinical Data Acquisition and Cleaning Support:

Develop and maintain SAS programs to perform database integrity checks and work with Data Managers to address data issues and queries for ongoing data cleaning and review.

Support data acquisition of non-CRF data by developing SAS programs to reconcile the CRF and non-CRF data and performing data integrity checks of the non-CRF data.

Develop SAS programs to generate data listings, summary tables, and graphs for ongoing data cleaning and scientific data surveillance reviews (safety, missing data, trending and signaling, etc.).

Develop SAS programs to generate Patient Profiles to support trial subject case review activities.

Document data and programming information in accordance with Everest company SOPs and WIs; and achieve audit readiness during and at the end of the clinical trials for internal and external quality and compliance audits.

Achieve a high rating for each of the defined Everest company and trial Sponsor-specific statistical programming key performance indicators.

Maintain current knowledge of pharmaceutical clinical research industry standards, conventions, and regulatory requirements, as well as the knowledge of clinical trial Sponsor-specific requirements when applicable.

Comply to Everest company-specific and clinical trial Sponsor-specific training requirements.

Develop and provide expertise in other programming and system administration areas when required.

Qualifications and Experience:

A Master's or Ph.D. Degree in statistics, biostatistics, epidemiology, public health, bioinformatics, mathematics, and computer sciences, with SAS certified Base, Advanced, and Clinical Trials Programmers are highly preferred; with exposure/experience in clinical trial statistical programming and/or data analysis is desirable.

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