gossamerbio

Senior Statistical Programmer

Summary Description

Responsible for providing statistical programming support for the Biostatistics and Data Management functions for all clinical trials and regulatory submissions. Works closely with Biostatisticians and Data Managers to create SAS programs for independently validating selected tables, listings, and figures produced by programming vendors, for ad-hoc analyses, and to assist with data cleaning and query generation. Independently produces selected ADaM files for analysis preparation and for validation of CRO CDISC work. Serves as a contact for programming activities being performed at CROs.

Key Responsibilities

- Provide SAS programming support to all clinical studies
- Manage programming CROs providing oversight for programming deliverables
- Provide QC support to selected CRO deliverables and to any internally-produced outputs
- Review and approve SAS programming instructions and CDISC/ADaM specifications
- Ensure consistency across programming methods in similar studies within a program
- Provide project management expertise, as needed, to insure quality and timely completion of study milestones
- Create programming related SOPs, as necessary

Education & Experience

- Bachelor's Degree equivalent with a minimum of 8 years of experience in SAS programming with at least 6 of those in a clinical research setting, including academic and/or industry experience in all phases of clinical research
- Excellent SAS programming skills including knowledge of SAS ODS graphical procedures such as PROC SGPLOT and the graphics template language (GTL)
- Knowledge of pharmaceutical and regulatory requirements, procedures, and policies with a minimum of 4 years of pharmaceutical experience
- Knowledge of GCP, ICH, 21 CFR part 11, and other Guidance documents and policies related to clinical trials operations requirements
- Knowledge of CDISC and ADaM dataset structures and requirements
- Knowledge of all aspects of clinical drug development (Phase 1-4)
- Experience working with and managing a CRO partner
- Excellent computer skills; strong verbal and written communication skills
- Ability to work well in a team environment as a contributor
- Open, engaging, and transparent work style
- Ability to competently manage multiple competing priorities, switching priorities quickly as needs change. Must be comfortable working in a very fast-paced environment