Manager/Senior Manager, Programmer

We are looking for a technically strong SAS programmer who can collaborate across Data Management and Biostatistics functions for key activities including individual protocols, integrated databases for electronic submissions, vendor oversight of SAS programming services, and in-house ad hoc analyses as needed.

Key Responsibilities:

- Accountable for the oversight of programming activities that are outsourced to the company's CROs, external vendors, and consultants
- Provide programming support for ad-hoc and in-house analyses
- Collaborate with other statistical colleagues and study personnel to provide input to statistical analysis plans.
- Assist in and/or be accountable for selecting statistical methods for data analysis, authoring the corresponding sections of the analysis plan, and conducting the actual analysis once a reporting database is created.
- Collaborate with data management in the planning and implementation of data quality assurance plans.
- Maintain proficiency with respect to SAS programming and statistical methodology and in applying new and varied methods.
- Effectively justify methods selected and implement previously outlined analysis plans.
- Conduct peer-review of work products from statistical colleagues.
- Effectively utilize current technologies and available tools for conducting the clinical trial analysis.
- Communication of Results and Inferences
- Collaborate with other statistical colleagues to write reports and communicate results.
- Responsible for assisting in the communication of study results via regulatory submissions, and manuscripts, as well as for communicating one-on-one with key customers.
- Assist or respond to regulatory queries working in collaboration with other statistical colleagues.
- Contribute to the development and maintenance of the statistical computing environment to support global usage
- Complete additional tasks and/or activities as requested and/or required in order to ensure the successful achievement of department and company goals

Qualifications:

- Master’s degree in Statistics or Biostatistics with 5+ years of Industry clinical statistical analysis/programming experience
- Proficiency in statistical programming languages/software such as SAS, R, Spotfire etc.
- Good communication skills; ability to work in a team environment with medical personnel, clinical monitors, statisticians, data managers and medical writers
- Knowledge of FDA/ICH guidelines and industry standard practices regarding data capture, clinical data structure, relational database, data processing, analysis

programming, and data exchange with alternate formats; FDA submission experience is highly desirable
- Knowledge of SAS to produce derived analysis datasets and TFLs
- Proficiency in quick visualization tools like Spotfire and JMP
- Understanding of the requirements for SDTM, ADaM, Data Definition Table, and e-submission
- Good understanding of clinical data and pharmaceutical development. Knowledge of statistical terminology, clinical tests, and protocol design.
- Experience managing programmers, preferred.
- Interpersonal/teamwork skills for effective interactions
- Self-management skills with a focus on results for timely and accurate completion of competing deliverables
- Demonstrated problem solving ability and attention to detail
- Work with external vendors and third party organizations and provide oversight to outsourced work.

Please submit resume to Soleno Therapeutics, Inc., hr@soleno.life