spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Senior Statistical Programmer

SPAULDING CLINICAL aims to be the clinical research organization by which all others are measured. Pioneering in our approach to redefining how the industry perceives and achieves success; passionate in our pursuit of ingenious solutions that mitigate risk; loving in our care for our volunteers, customers and employees; and heroic in our ambitions to ensure the health and safety of people around the globe - Spaulding Clinical is taking ***research beyond results*** to create a marketplace of safer drugs.

Original Date: 13 Sep 2012

Revision Date:

Job Summary:

Senior Statistical Programmer role will work as a part of a multi-dimensional project team focused on delivering quality and timely deliverables for a variety of pharmaceutical and biotechnology clients. The Senior Statistical Programmer will build the appropriate programs in order to create SAS datasets from the clinical database and other data sources as outlined in the clinical study's protocol, Clinical Data Management Plan, or Statistical Analysis Plan. The Senior Statistical Programmer will develop SAS macros, templates and utilities for data cleaning, reporting and analysis. The Senior Statistical Programmer has working knowledge of SDTM/ADaM Guidelines and Requirements and is comfortable communicating with all levels of the internal team and external sponsors alike. The Senior Statistical Programmer will mentor junior members of the programming team. The Senior Statistical Programmer will function without daily oversight in the performance of the specified duties.

Essential Duties and Responsibilities:

- Review CRF's to ensure consistency with protocol and adequacy to collect the data to meet the objectives defined in the statistical section of the protocol.
- Review CRF annotations and database data specifications
- Creates derived-analysis datasets. Executes analyses specified in the protocol or the Statistical Analysis Plan (SAP) under the guidance of the project statistician.
- Works closely with the Biostatistics and Data Management members on various clinical projects.
- Interface with data management and clinical to identify and program edit checks per the Data Validation Plan/Data Management Plan and study management reports using SAS.
- Write SAS programs to generate tables, listings, and figures and analysis datasets.
- Perform validation of the programmed analysis datasets, tables, listing and figures.
- Perform analyses defined in the statistical analysis plan as well as ad hoc analyses as requested.
- Participate in the preparation of clinical and statistical summary reports.
- Perform statistical QC of final reports.

- Performs all SAS programming required for clinical trial analysis and reporting, and various other programming tasks
- Demonstrates strong SAS programming skills, participates in protocol team and some project team interactions. Builds successful relationships and seamless interfaces at the protocol/project team level. Provides timely and effective communication to the programming and statistics leads.
- Mentor junior programmers
- Participate in Sponsor calls (when appropriate)

The Statements made in the job description are intended to describe the general nature and level of work being performed by people assigned to this job. These statements are not intended to be an exhaustive list of all responsibilities, duties and skills required of people assigned to this job.

Skills/Qualifications:

- Experience with SAS/BASE, SAS/STAT, SAS/MACRO, SAS/GRAPH, SAS ODS
- Strong DATA step programming skills
- PROC REPORT familiarity and the handling of coding dictionaries preferred
- Ability to read, write, and interpret the English language.
- Strong communication skills, both written and verbal
- Maintains strong attention to detail in high-pressure situations
- Solid understanding of business practices with fundamental understanding of project management methodology
- Requires excellent computer skills

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to sit, stand, walk, reach with hands and arms, and use hands along with fingers, to handle or feel.
- Ability to lift and/or move up to 25 pounds.
- Specific vision abilities required by this job include clarity of vision both near and far.
- Ability to identify and distinguish colors.

Hazards:

- Potential for exposure to toxic or caustic chemicals
- Potential for exposure to blood borne pathogens

Education and Experience:

- Experience in Biostatistical Analysis & SAS Programming for clinical trials in the medical device, pharmaceutical or biotechnology industry. Five to eight years of programming experience in a clinical trials environment
- Degree in Information Management, Computer Science, Mathematics, Statistics, or a scientific discipline.

Spaulding Clinical Research management has the discretion to hire personnel with a combination of experience and education which may vary from the above listed skills and qualifications.