spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

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: 14 Aug 2013

28 Apr 2016

Job Summary:

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 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, and/or Statistical Analysis Plan. The Statistical Programmer will develop SAS macros, templates and utilities for data cleaning, reporting and analysis. The Statistical Programmer has general knowledge of Clinical Data Interchange Standards Consortium (CDISC) Guidelines and Requirements.

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 and SAP.
- Review CRF annotations and database data specifications.
- Creates derived-analysis datasets utilizing the ADaM standard of CDISC. Executes analyses specified in the protocol or the Statistical Analysis Plan (SAP) under the guidance of the project statistician.
- Works closely with the Biometrics members on various clinical projects.
- Interface with Data Management and clinical teams 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 SDTM domains, listings, and figures (TLFs) and analysis datasets (ADaM).
- Perform validation of the programmed SDTM and ADaM as well as TLFs.
- Create SDTM annotated CRFs as well as define.xml and reviewer's guides to support electronic submission (eSUB) requirements.
- Perform analyses defined in the statistical analysis plan as well as ad hoc analyses as requested.

- Perform 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.

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
- 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.

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. Three to five years of programming experience in a clinical trials environment
- Degree in Information Management, Computer Science, Mathematics, Statistics, or related 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.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I further understand that Spaulding Clinical may change, add or delete any essential duties and responsibilities described at its discretion with or without prior notice.

Name (Printed) Date

Signature