JOB TITLE: Biostatistician/SAS Programmer
DEPARTMENT: Clinical Operations

Under the direction of the Director of Clinical Operations, the Biostatistician/SAS Programmer will be responsible for building programs to create SAS datasets and providing statistical expertise on the design, analysis and interpretation of data for Clinical Endpoint studies. They will represent the statistic function in support of clinical studies by providing accurate statistically valid deliverables based on study protocols, statistical analysis plans and regulatory requirements.

RESPONSIBILITIES:

- Creation of SAS programs to generate tables/listings/figures and submitting the results of clinical trials for investigational medications
- Generate and define documents, annotated CRFs, and reviewer's guides per CDISC and FDA specifications and guidelines
- Support data management by generating data listings
- Design and prepare regulatory submission-ready packages
- Provide technical leadership, problem-solving of moderate to high complexity
- Demonstrate expertise in SAS language, procedures, and options commonly used in clinical trial reporting
- Create all files, documents, and analyses necessary to support electronic submissions
- Contribute to the efficient planning, execution, and reporting of clinical studies
- Review protocols to ensure statistical integrity and consistency
- Review and provide input into critical documents, such as CRFs and Data Validation Plans
- Develop statistical analysis plans and tables, listings, and figure specifications
- Perform statistical analyses for clinical and nonclinical studies
- Contribute to CSRs

REQUIREMENTS:

- Demonstrated ability to effectively manage and prioritize multiple programs
- Understanding of clinical data management applications and systems
- Experience in developing data management procedures and processes
- Excellent written and oral communication skills

- Proficient knowledge of medical terminology and expertise with GCP and regulatory compliance guidelines for clinical trials
- Solid understanding of clinical drug development process
- High attention to detail and accuracy and ability to manage multiple project teams
- Excellent prioritization and organizational skills and demonstrated ability to delegate appropriately
- Ability to work on extremely complex problems where analysis requires evaluating various factors
- Ability to exercise independent judgment in developing methods, techniques and evaluation criteria for obtaining results
- Advanced people management skills and positive flexible outlook
- Excellent interpersonal communication skills and works effectively on cross-functional teams

EDUCATION REQUIREMENTS:

- Masters degree in Statistics/Life Sciences/Computer Sciences or related field with a minimum of 5-7 years of experience in a biopharmaceutical setting (industry and/or CRO), specifically in Clinical Trial Design
- Knowledge in theoretical and applied biostatistics
- Knowledge of the SAS programming language, especially basic SAS procedures (CIMPORT, COMPARE, CONTENTS, CPORT, EXPORT, FORMAT, FREQ, IMPORT, MEANS or UNIVARIATE, PRINT, REPORT, SORT, SQL) and the DATA step and the ability to perform programming tasks in a SAS/Oracle environment
- Experience in handling large data sets, awareness of data quality issues, and familiarity with programming in a research environment

NOTE: This job description is not intended to be all inclusive. Employee may perform other related duties as delegated to meet the ongoing needs delegated of the company.