JOB TITLE: Biostatistician
DEPARTMENT: Clinical Operations

Working within the Clinical Operations Department, The Biostatistician is responsible for providing statistical expertise in the design, analysis and interpretation of data for clinical trials. They will represent the statistic function in support of clinical studies by providing accurate and statistically valid deliverables based on study protocols, statistical analysis plans and regulatory requirements. This position will also assist in providing SAS programming support to the Programmer Analyst(s).

RESPONSIBILITIES

- Ensure adherence to guidelines, SOPs and compliance with regulations on all projects
- Function as a statistical resource for staff on such topics as study design, sample size calculations, analysis methods
- Contribute to the development or improvement of systems to assure the timely provision of high-quality statistical services
- Work closely with data management and clinical operations personnel to determine statistical support requirements and to develop and validate study-specific data capture activities.
- Responsible for vendor management of the statistics function, statistical programming, and TLFs quality/standards
- Propose creative solutions to identified problems.
- Develop Statistical Analysis Plans to meet regulatory standards, table shells, analysis specifications, and statistical reports; conduct statistical programming primarily in SAS; oversee validation process.
- Creation of SAS programs to generate tables/listings/figures and create SAS datasets
- Provide data analysis, tables and graphics for statistical reports provided to sponsors
- Prepare datasets for analysis by merging files, creating analysis variables, editing data, and developing documentation
- Interpret results of analysis for a wide variety of audiences
- Contribute to the design and use of appropriate data collection and quality control methods
- Promote good statistical practice for the support of sound scientific judgments
- Ensure schedule, budget and quality commitments are met for the client, within the scope of control.
- Communicate project/team issues to project managers
- Contribute to presentations, including preparation, assembling slides, and speaking

- Interact as needed with clients, auditors, inspectors, subcontractors, consultants, and other individuals or departments. Participate in meetings with prospective clients
- Provide scope of project and relevant information to support the creation of proposals.

REQUIREMENTS:

- Minimum of 3-5 years of experience in a biopharmaceutical setting (industry and/or CRO), specifically in Clinical Trial Design
- Expertise in SAS programming language
- Knowledge in theoretical and applied biostatistics
- Ability to organize and manipulate large datasets
- Ability to express complex statistical concepts and technical information
- Excellent organizational and time management skills with the ability to work independently and in a team environment
- Excellent written and oral communication skills including grammatical/technical writing skills
- Effective interpersonal, mentoring, and leadership skills.
- Strong problem-solving capabilities.

EDUCATION REQUIREMENTS:

- Master's degree or PhD in Statistics/Life Sciences/Computer Sciences or related field is required

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

I have received a copy of the job description for my position. I have reviewed this job description and I understand my job duties and responsibilities.

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Employee Signature Date