SUNOVEE INC

JOB DESCRIPTION (JD)

SENIOR STATISTICAL PROGRAMMER
STATISTICAL PROGRAMMING

QUALIFICATIONS:

- Bachelor's or Master's degree in Statistics, Biostatistics, Computer Science, Life Sciences, or a related field, with a minimum of 3 years of pharmaceutical, medical device, or CRO-related experience as a SAS programmer analyzing clinical trial data
- Excellent working knowledge of SAS (including macro language, Proc SQL, ODS, SAS/GRAPH, and SAS/STAT)
- Good working knowledge of CDISC SDTM and ADaM models
- Experience in integrating ISS/ISE data preferred
- Experience using other statistical packages (e.g., S-Plus, R) is a plus
- Knowledge of and ability to adhere to GCP principles and relevant regulatory requirements
- Aptitude for quantitative problem-solving with the capacity to troubleshoot and work independently
- Comprehensive knowledge of technical and regulatory requirements
- Expertise in techniques and processes used to validate programming and documentation requirements

RESPONSIBILITIES:

- Provide SAS programming support for analyzing clinical trials, supporting registrations, and creating reports for publications and other ad hoc analyses
- Develop SAS programs to generate TLFs that meet requirements using SAS, SAS Macros, SAS/STAT, SAS/GRAPH, and SAS/SQL within applicable timelines
- Interact with statisticians and interdisciplinary teams regarding timelines and analysis scope of deliverables
- Develop, validate, and maintain macros and tools for general use within the Statistical Programming department to enhance efficiency and quality of output
- Provide technical leadership and support to members of the Statistical Programming department as required
- Apply and promote good programming practices

- Generate, validate, and/or review SDTM domains and ADaM datasets and associated specifications
- Generate, validate, and/or review tables, figures, and listings to support the statistical analysis of clinical trial data for regulatory submissions and publications
- Maintain complete and auditable documentation of all programming activities
- Manage programming, testing, and documentation of SAS global utility programs and tools in accordance with standards and validation procedures
- Review CRFs, edit check specifications, and table, figure, and listing mock-ups
- Manage, generate, and/or review acrf.pdf, define.xml, define.pdf, and reviewer's guide documents
- Forecast work for the team, provide a vision of ongoing project objectives and milestones, and clarify upcoming projects
- Independently coordinate and manage the preparation, execution, reporting and documentation of projects within a Programming group.

REQUIREMENTS:

- Ability to design and develop complex programming algorithms; ability to comprehend analysis plans that describe methodology to be programmed; understanding of statistical terminology and concepts
- Minimum of 3 years of clinical trial programming experience in the biotechnology, pharmaceutical or health related industry.
- Excellent organizational skills, time management, and ability to coordinate workload and meet established deadlines
- Ability to work independently and collaboratively
- Ability to prioritize with minimal daily instruction
- Ability to think strategically to improve current processes
- Works effectively with cross-functional groups, study teams, and vendors
- Learning agility and scalability to take on increasing responsibility as Intercept grows
- Ability to follow guidelines and specifications on validation procedures and data transfer procedures
- Able to set realistic timelines for assigned tasks and follow through to completion

WORK LOCATION: USA (REMOTE WORK, preferably from North Carolina State)