Associate Director/Director, Statistical Programming

This newly created position will provide hands-on programming support to Bolt's programs as well as contributing to the development of Bolt's clinical programming function and processes. This position will report to the Vice President, Biometrics and title will be commensurate with experience.

Responsibilities

- Independently develops, troubleshoots, and maintains statistical programs
- Provides comprehensive programming leadership and support to clinical development teams
- Ensures quality of deliverables by consistently applying analysis and reporting standards, and driving compliance with regulatory requirements, corporate and departmental SOPs and work practices
- Drives the development and implementation of innovative strategies and technologies for clinical trial programming
- Develops unambiguous and robust programming specifications for internal and external programming work
- Provides technical guidance to vendors around project conventions, standards, practices, and specifications to ensure integrated computing solutions
- Reviews planning documents (e.g. statistical analysis plans, data presentation plans, data review plans) to ensure clarity, integrity and compliance with requirements and standards
- Build and manage regulatory compliant computing environment, statistical programming SOPs

Qualifications

- Graduate degree in statistics, biostatistics, mathematics, computer science or equivalent experience
- Minimum of 10 years (for Director or 8 years for Associate Director) of clinical/statistical programming experience within pharmaceutical clinical development with experience that includes leading programming efforts to support regulatory filings (e.g. US, EU, Japan)
- Minimum 5 years (for Director or 3 years for Associate Director) of experience in managing technical professionals in a regulated environment
- Extensive knowledge of SAS software (i.e. Base, Stat, Graph components) and general computing techniques in addition to knowledge of R or other statistical software packages
- Significant knowledge of the drug development process, clinical trial methodology, statistics and relevant regulatory requirements for drug approval
- Demonstrated ability to operate and lead in a dynamic organization, build successful working relationships and effective stakeholder management in an environment that requires diverse educational and functional expertise.
- Able to adapt quickly to the changing needs of the organization
- Able to organize multiple work assignments and establish priorities
- Excellent verbal and written communications skills; able to communicate proactively and effectively