

Job Posting Description

The Senior Statistical Programmer provides technical expertise for the conduct of clinical trials, might act as an internal subject matter expert in specific areas providing technical support and expert advice, and works independently to support various programming activities related to the analysis and reporting of clinical study data. In addition, the Senior Statistical Programmer can fill the Statistical Programming Coordinator role on projects, and liaise with sponsors, Data Operations Leads, and other functional areas as required. General areas of responsibility also include: import/export programming specification development, test data creation and test data entry, import/export programming functional testing, as well as mapping specifications to support relevant data standards.

Key Accountabilities

- Deliver best value and high quality service
- Ability to fill Statistical Programming Coordinator role on projects. The Statistical Programming Coordinator will: Input into and negotiate statistical programming timelines. Ensure that timelines are adhered to, Coordinate and lead a statistical programming team to successful completion of a study within given timelines and budget, Monitor project resourcing, project budgets, and identify changes in scope
- Interact with Sponsors as the key contact with regard to statistical programming issues
- Provide technical support and advice to the internal team
- Check own work in an ongoing way to ensure first-time quality
- Ensure quality control (QC) on all process and technical activities related to derived dataset, table, listing, and figure programming in accordance with corporate quality standards, WSOPs/Guidelines, ICH-GCP and/or other international regulatory requirements are performed
- Coordinate project start-up activities, including Unix/PMED project area set-up, creation of global programs, tracking spreadsheets, and required documentation
- Assist in the production and QC of analysis plans, produce and QC TLF mock-shells, derived dataset specifications, programming specifications, and other process supporting documents
- Use efficient programming techniques to produce and/or QC derived datasets tables, figures and data listings
- Understand regulatory requirements concerning industry technical standards and implications for the department
- Provide input into monthly PERFORM forecasts and monitor the completion of forecasted units.
- Create standard macros and applications to improve the efficiency of the department
- Maintain all supporting documentation for studies in accordance with WSOPs/Guidelines to ensure traceability and regulatory compliance
- Be trained in sponsor WSOP's and disseminate knowledge to project team members as appropriate.
- Proactively participate in and/or lead process/quality improvement initiatives
- Work closely with the Quality Management Groups (QMG) to ensure compliance with WSOPs/Guidelines, ICH-GCP and any other applicable local and international regulations and participate in internal/external audits and regulatory inspections as required

- Develop wider knowledge of SAS and other relevant programming languages and processes within the GRO, Biostatistics, and Medical arenas
- Maintain and expand local and international regulatory knowledge within the clinical industry.
- Assist project teams in the resolution of problems encountered in the conduct of their daily work
- Provide relevant training and mentorship to staff and project teams
- Lead and supervise and/or create, implement and execute import and export programs, in either standard format, client specific format or CDISC compliant format depending on nature of request
- Develop mapping specifications for data exports in accordance with applicable standards

***Job Posting Qualifications**

Skills

- Proficiency in SAS
- Knowledge of the programming and reporting process
- Knowledge of WSOPs/Guidelines/System Life Cycle methodologies, ICH-GCP and any other applicable local and international regulations such as 21 CFR Part 11 and proven practical application
- Demonstrate ability to learn new systems and function in an evolving technical environment
- Strong leadership ability
- Attention to detail
- Ability to successfully work together with a (“virtual”) team (including international teams as required) as well as independently
- Demonstrate strong organizational skills, ability to manage competing priorities, and be flexible to change
- Business/Operational skills that include customer focus, commitment to quality management and problem solving
- Good business awareness/business development skills (including financial awareness)
- Ability to create, maintain and define strategies to improve the efficiency of running a clinical trial.
- Work effectively in a quality-focused environment
- Demonstrate commitment to refine quality processes
- Effective time management in order to meet daily metrics or team objectives
- Shows commitment to and performs consistently high quality work

Education

- Educated to degree level in a relevant discipline and/or equivalent work experience

Language Skills

- Competent in written and oral English
- Excellent communication skills

Minimum Work Experience

- Relevant Clinical Trial industry experience

Contact

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