

**Role:** Sr. Statistical Programmer

**Location:** CT

**Full Time**

**Salary:** \$80-120K

**POSITION PURPOSE:**

- Accountable for the provision of standard and non-standard data sets, tables, listings and figures based on the final synopsis and SAP that are required for the study reports, submissions and product defense
- Delivers against the overall protocol timeline, cost and quality goals through matrix communication within the Study Team
- Clearly specifies requirements to external resources and to assure the quality of deliverables provided by external resources
- Champions operational excellence to provide continuous improvement of processes and sharing of best practices across TAs
- Tracks milestones against project timelines
- Communicates effectively not only within the teams and functional lines but also with the external resources

**Major Duties:**

- Serve as the clinical programming representative on drug development project teams, working closely with project team leaders and CPW leadership to establish strategy, time lines, and project management for the analysis and reporting of clinical study data
- Actively support the CPW Sourcing model where programming is primarily performed by Shanghai or FSP partners and overseen by Internal Programmers who are the face for the team. Accountable for the delivery of tables, listings and figures through FSP and low-cost providers
- Makes decisions regarding operations within relevant therapeutic area, including project plans, specifications and resource allocation, allowing time and resource for ESUB activities
- Oversee the development of standard and non-standard datasets, tables, listings, and figures based on the final protocol synopsis and SAP that are required for the clinical study report, submissions and product defense
- Adhere to TA standards, aligning phase I to IV programming standards to develop repositories to support enhanced clinical trials, safety first initiative, commercial and litigation support
- Prepare for an ESUB by ensuring that value added datasets and their programming plans meet the FDA's ESUB requirements as well as study reporting needs. Contribute to the production of ESUB components when required either directly, by providing additional information or by way of review
- Provides filing, approval and regulatory programming support for all aspects of a submission
- Aligns cross-functionally with project team members to address project-related goals
- Provides end game report and IB tables, listings and figures

## Requirements

**Training & Education Preferred:**

Minimum: BS in Statistics with 4-6 years relevant experience or equivalent experience

Desirable: MS in Statistics with 6-9 years industry experience or equivalent experience

- At least 3 years experience with SAS
- At least 3 years of statistical programming experience including the analysis and reporting of clinical trial data
- At least 3 years experience working in a disciplined systems programming environment; experienced with Software Development Life cycle (SDLC) and regulatory validation requirements including 21 CFR Part 11

**Prior Experience Preferred**

- Demonstrated knowledge of clinical development and regulatory submission processes
- Expert knowledge of base SAS, SAS macro language, graph, FSP, AF, STATS, SQL as well as other programming languages, etc
- Knowledge of FDA guidance on electronic submissions
- Able to manage multiple projects simultaneously
- Experience with SAS statistical procedures
- Knowledge of systems testing processes and documentation
- Strong interpersonal, verbal and written communication skills
- Demonstrated ability to work collaboratively on multidisciplinary teams
- Leadership, communication and project management skills required