Study Lead Programmer

We are seeking a Study Programmer for a recently expanded five year FSP contract with a well-respected, leading biotechnology firm. This high visibility technical role is responsible for directly managing a team of programmers, as well as providing appropriate guidance to other programmers. You will be tasked with ensuring that all timelines and quality standards are met and that all tasks (e.g. all programming related activities of a study) assigned to your team are aligned with the respective programmers' abilities. Significant hands-on statistical programming is a key expectation for the role.

Additional responsibilities include:

- Participate in establishing the programming scope for a deliverable with study statistician and study team
- Participate in establishing detailed timelines that will ensure timely deliverable
- Write protocol specific programming specifications
- Review and propose data specification for assigned protocols for SDTM and ADaM data
- Manage individual programmer work assignments to assure timely, high quality deliverables
- Review and critique QC documentation
- Provide technical leadership and guidance for study programming team
- Coordinate and monitor data issue reporting and resolution
- Coordinate with other leads to provide consistent deliverables across the assigned projects
- Serve as primary interface to study team and Amgen CDISC Consultancy and Implementation (CCI) group, if necessary
- Manage technical aspects of project (e.g., create/manage computing environment, lookup tables)
- Manage project tracking tools and provide periodic status reports to Company team
- Provide mentoring for all newly added FSP programmers

The position can be home based or in one of our offices in Cambridge, MA; Waltham, MA; or Chesterbrook,PA.

Qualifications and Experience

You will have a BA/BSc or higher degree in Statistics, Mathematics, Computer Science, Life Sciences or other related scientific subject, and a minimum of 5 years of relevant career statistical programming experience in a clinical development environment; six or more years strongly preferred. Additionally, we require:

- Ability to work effectively and successfully in a globally dispersed team environment with cross-cultural partners
- Ability to work effectively on multiple tasks or projects
- Willingness and ability to provide guidance to team members on technical and process questions
- Thorough understanding of clinical trial processes, from data collection to analysis reporting
- Proven record of superior statistical programming and problem solving skills within clinical development environment
- In-depth knowledge on latest CDISC SDTM standards and familiar with CDISC ADaM and Define standards along with strong ability to implement all aspects of CDISC
- Prior experience and ability to lead and manage programmers in the successful and timely completion of all programming related activities for a study end to end
- Excellent oral and written English communication skills

Compensation & Benefits

We offer a competitive salary-based package, bonus, comprehensive medical and dental benefits, plus a contributing 401K plan.

Contact

To apply, contact Bob Davis at Cytel (bob.davis@cytel.com).