Lead SDTM Implementer

We are seeking a Lead SDTM Implementer for a recently expanded five year FSP contract with a well-respected, leading biotechnology firm. This high visibility role will work with the CDISC Consultancy and Implementation (CCI) team, a group within the client's Global Statistical Programming department responsible for supporting the compliant and consistent adoption of the CDISC Study Data Tabulation Model (SDTM).

Additional responsibilities include:

- Provide support for new and ongoing studies and drive close collaboration with other CDISC Consultants and Implementers, Statistical Programmers, Global Librarians, and Data Stewardship Representatives
- Develop compliant and consistent CDISC SDTM datasets, perform CRF SDTM annotation and CDISC Controlled Terminology Management, and maintain all controlled and tracking documentation
- Provide technical, process, and project management leadership for assigned projects and the group in general
- Overall maintenance and coordination of CDISC standards efforts, ensuring maximum reuse of applied standards, involvement in ongoing process improvement efforts, and working with teams to provide technical and process guidance
- Stay current with the evolution of all CDISC SDTM standards and may also be involved in creation and maintenance of process documentation

There is the possibility that you could be integrated into a study team to lead the SDTM implementation work, with responsibility for managing the task assignments to SDTM Implementers and study 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 five years of relevant career statistical programming experience in a clinical development environment; six or more years highly desirable. Additionally, we require:

- Excellent SAS data manipulation skills
- Familiarity with drug development life cycle and experience with the manipulation, analysis and reporting of clinical trials data
- Ability to work effectively and successfully in a globally dispersed team environment with cross-cultural partners

- Excellent oral and written English communication skills
- Ability to provide quality output and deliverables, in adherence with challenging timelines
- Willingness and ability to learn and follow standard processes and procedures
- Ability to develop SAS Macros (specification/coding/testing) in accordance with standard practice
- Ability to apply source code control procedures for custom SAS Macro Development
- Ability to lead and manage a team of SDTM Implementers in the successful and timely completion of all related SDTM activities for a study end to end
- Project management experience – prioritizing, resourcing, following timeline, issue tracking
- Strong SQL and SAS programming skills with respect to data transformation
- Detailed knowledge of CDISC SDTM standards and the principles on which it is founded
- An understanding of where the process of producing SDTM datasets fits within the overall statistical programming workflow
- Ability to code to conventions provided by Company/CDISC
- Ability to identify data issues that affect programming decisions or the integrity of results
- Hands-on experience on CRF annotation with SDTM mapping
- Experience managing SDTM controlled terminology
- Ability to quickly develop a detailed understanding of study protocols, annotated CRFs, controlled terminology, and raw datasets
- Prior leadership or management position

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).