Study Statistician

We are seeking a Study Statistician for a recently expanded five year FSP contract with a well-respected, leading biotechnology firm. This is a high visibility role with significant interaction with the client's statisticians.
Specific responsibilities include:

- Provide statistical contributions, statistical review and quality control of Statistical Analysis Plans (SAPs), Table, Figure, and Listing (TFL) shells, Submission Data File (SDF) specifications (SDTM and ADaM), other key-study related documentation, protocol deviations, Data Quality Review (DQR), and other communications
- Assist in cross-functional study start-up activities, including but not limited to CRF review, database specifications review, Interactive Voice Response System (IVRS) specification review
- Complete statistical analysis of individual studies/projects
- Review TFLs created by statistical programming for consistency and accuracy
- Collaborate with the study programming team for study deliverables
- Be familiar with all Company's policies, SOPs and other controlled documents related to study activities noted above
- Assist with study and systems audits conducted by Company GCA and external bodies

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 Masters or Doctoral degree in Statistics/Biostatistics or other subject with high statistical content. Masters level candidates must have two years post-graduate experience in the pharmaceutical industry or medical research with four years preferred. Doctoral level candidates must have one year post-graduate experience in the pharmaceutical industry or medical research with two years preferred. Additionally, we require:

- Communication of statistical information (written and oral)
- Strong understanding of statistical concepts related to the design and conduct of clinical studies
- Strong ability to apply statistics in the analysis of clinical trials
- Excellent oral and written English communication skills
- Designing, analyzing and/or reporting clinical trials within Pharmaceutical/Biotechnology/Public Health setting in Industry, Government or Academia
- Leadership of at least 1 study/project with minimal oversight

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- Authored a protocol, DRT/DMC, SAP, CSR, or Research Project Plan (RPP)
- Strong knowledge of current CDISC standards for SDTMs and ADaMs

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).

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