Clinical Statistical Analyst

Location: Frederick, Maryland

Industry: Consulting – Drugs/Biologics/Devices

Term: Full time, Permanent

Reports to: Associate Directors, Biostatistics

BioStat Solutions, Inc. (BSSI) is a statistical consulting corporation in service to the pharmaceutical, biotechnology and biodefense industries. BSSI’s key service areas include the development and implementation of analytical strategies for biomarker studies, medical countermeasure development, medical device/(companion) diagnostic studies and regulatory approval.

Job Objective:
Provide statistical programming, including data analysis and interpretation in accordance with project and regulatory requirements along with summarizing findings in support of client objectives.

Details:
- Provide statistical programming in a team environment to address clinical objectives for clients across a variety of clinical studies.
- Adhere to company and regulatory guidelines in analysis and reporting of statistical findings.
- Understand and consider complexity of clinical studies while providing analysis of data.
- Conduct work in accordance with BSSI standard operating procedures (SOPs), BSSI QA/QC policies, client-specific requirements and applicable regulatory guidelines.
- Develop optimal models for analysis and interpretation of clinical findings.
- Create extensive SAS programs with sufficient detail and ease of interpretation to implement potential complex designs of biomarkers, and have a thorough knowledge to implement programs for linear regression models, linear mixed models, generalized linear models, generalized linear mixed models, non-linear models, survival analysis, simulation studies (e.g. MCMC) and power/sample size estimation.
- Responsible for understanding and adhering to statistical methodologies as set forth in project requirements (e.g., Statistical Analysis Plan [SAP]) and ensuring methodologies are being implemented appropriately.
- Generate tables, figures and listings (TFLs) for presentation and interpretation of results in accordance with project requirements.
- Assist in development of documents or presentations as needed.
- Identify, interpret and communicate meaningful findings to key individuals (i.e. answer the “so what” questions).

Qualifications:
- M.S. Degree in Statistics or Biostatistics PREFERRED or B.S. Degree in Statistics, Biostatistics or closely related field WITH minimum of 5 years clinical experience.
- 1-3 years of statistical experience in biotech, pharma or government.
- The ability to independently write SAS programs in adherence to clinical and statistical objectives
- Knowledge of clinical terms, clinical study designs and the drug and/or device approval process.
- At least 3 years of SAS programming experience and an independent working knowledge of SAS macros is required; in addition, proficiency in R is preferred
- Knowledge of the drug/device approval process is required, statistical genetics and/or personalized medicine experience preferred
- Proven ability to work independently and in a team environment
- Excellent analytical and problem-solving skills
- Excellent written and verbal communication skills
- Qualified candidates must be legally authorized to be employed in the US

BioStat Solutions, Inc. is a voluntary Equal Opportunity Employer

Please apply to hr@biostatsolutions.com www.biostatsolutions.com