

Please contact Robert Ossakow robert.ossakow@covance.com, ph: 410-628-8869

Business Title Biostatistician  
Requisition ID 10681BR  
Job Category Other  
Locations USA - Conshohocken, PA  
Shift 1

**Job Description** \* Responsible for development of Statistical Analysis Plans, to include statistical methodology, statistical programming procedures, definition of derived variables, data-handling rules and mockups.

- \* Responsible for Biostatistics' deliverables within assigned projects.
- \* Develop and coordinate QC procedures for Biometrics deliverables, ensuring activities are appropriate for effectively and efficiently delivering quality output within a specific project.
- \* Statistical analysis of clinical trial data and related decision making.
- \* Responsible for statistical input to statistical reports and Clinical Study Reports. Authorises final reports as one of Covance signatories.
- \* Statistical Analysis of data from observational studies and registries including data on patient reported outcomes.
- \* Analyze data employing advanced techniques such as propensity scoring, multiple imputation and signal detection techniques as appropriate
- \* Statistical analysis employing data mining techniques for pharmacovigilance including databases such ARIC, AERS, GPRD, etc). Methods include neural network approach, multi-item Gamma Poisson Shrinker algorithm etc.
- \* Provide statistical guidance in development of clinical research program and in design of individual studies as part of multi-disciplinary team; responsible for statistical input to protocol; approves protocol as signatory.
- \* Provide statistical input into design/review of format of CRFs.
- \* Supervision of less-experienced statisticians within project activities.
- \* Statistical/Biometrics lead for large global or other major programs.
- \* Prepare randomisation specifications; generate schedules; verify randomisation components (specification and schedule). Provide input into planning activities related to the preparation of, distribution of and access to randomisation and unblinding information.
- \* Project management activities for identified projects including financial, resource planning and utilisation, timelines and milestone management.
- \* Determine documentation requirements for Biostatistics' aspects of projects. Give guidance to support business and regulatory requirements including definition of appropriate documentation, storage/communication media, and retention/return of documents at study close-out.
- \* Provide statistical input into other disciplines' activities and participate in interdepartmental processes.

- \* Independent peer review of statistical deliverables, eg, protocols, Statistical Analysis Plans, Tables, Figures and Patient Data Listings, statistical reports, Clinical Study Reports.
- \* Provision of technical solutions and advice to Covance staff and to clients on statistical methodology and principles.
- \* Provide support for special committees, eg, DSMBs, including input/review of charters, and ensuring maintenance of appropriate blinding.
- \* SAS programming and related activities for the presentation and analysis of clinical trial data.
- \* Ensure mechanisms in place to maintain flow of appropriate information between disciplines on project team.
- \* Contact with client across multiple disciplines.
- \* Training and development of less-experienced staff within the department.
- \* Contribution to review and amendment of departmental processes and supporting documentation.
- \* Contribute to proposal activities and client presentations.
- \* Represent the department during audits.
- \* Carry out all activities according to appropriate Covance SOPs, working within the framework of the Quality Management System and to GCP.

**Education/Qualifications** \* An MSc or PhD in a statistics subject, preferably with a strong medical statistics component. Alternative academic qualifications are assessed for comparability.

**Experience** \* Approximately 1-5 years' postgraduate experience in the application of statistics to clinical trials, observational studies, and/or data mining

- \* Interpersonal and effective communication skills. Cooperative, team-oriented and proactive.
- \* Self-motivation.
- \* Ability to motivate others.
- \* The ability to work to tight deadlines while maintaining high standards
- \* SAS proficiency including use of a variety of statistical procedures eg, non-parametric analysis, linear and non-linear models, categorical data and survival analysis.
- \* Ability to adhere to strict guidelines & codes of practice.
- \* A good knowledge of the overall Clinical Trial process and of its application within Covance Clinical Development.
- \* Competence in the preparation of Statistical Analysis Plans, analysis, reporting etc across a variety of trials.
- \* Ability to explain statistical concepts to non-statisticians.
- \* Supervisory and organisational skills.
- \* A proactive approach to the management of day-to-day activities and actions that may affect Covance as a business.
- \* A professional approach at all times.