OVERVIEW

Junior Biostatisticians will work closely with statisticians and programmers to provide statistical services for analysis, reporting, and statistical programming specific activities. This may include development of statistical analysis plan, randomization schedule, conducting statistical analyses, validating programming and reporting output, and developing statistical analysis report. Junior Biostatisticians will also work on statistical programming for development of analysis datasets, and clinical tables, listings, and graphs specific to trial reporting requirements. Junior Biostatisticians will work as needed assuring that all client work has met or exceeded client expectations.

This position reports to management representative of the Biometrics & Data Solutions team.

MAIN INTERFACES

The Junior Biostatisticians will work with Eliassen statisticians, programmers, consultants and staff including representatives of IT, Sales and Recruiting.

In addition, Junior Biostatisticians will work with external clients and vendors.

KEY TASKS & RESPONSIBILITIES

- Provide statistical analysis services related to clinical trial. Fulfill the responsibilities of study statistician as required.
- Conduct the QC of statistical programmer's outputs; define analysis data specifications. If required, validate the statistical models used for programming.
- Act as support statistician - interact with programmers and statisticians and other relevant personnel. Draft statistical analysis specifications.
- Review the statistical analysis plan. Collaborate with principle statistician to ensure appropriate input for statistical analysis plan.
- Validate the programming deliverables and collaborate with applicable team members to rectify any issues related to statistical reporting and analysis.
- Wherever applicable, provide input in finalization of study specific data quality control plan and ensure appropriate data analysis and reporting.
- Wherever applicable, develop, validate and finalize the study specific list of table and table shells for clinical study reports and for study specific deliverables.
- Ensure that all comments from the clinical team with regards to statistical report delivered for study specific deliverables are being addressed appropriately.
- Analyze the data and review the outputs for deliverables including but not limited to blinded data reviews, and interim analyses.
- Conduct statistical analyses and develop statistical methodologies as per direction of management and senior statisticians.
- Develop SAS programs to generate analysis datasets, and trial specific reporting including but not limited to tables, listings, graphs, queries, and patient profile reports.
- Carry out rework as requested by supervisor or client representative
- Contribute to close –out evaluations and any discussion
- Ensure compliance with Clinical and industry quality standards, guidelines and procedures
- Other duties as assigned

CANDIDATE'S PROFILE

Education/ Language:

- Master in Statistics, Mathematics or biostatistics
- Excellent knowledge of English
- SAS® certification is preferred.

Professional Skills & Experience:

- Minimum 1 to 2 years in Pharmaceutical/Biotechnology industry or equivalent statistical consulting and statistical programming role
- Knowledge of clinical study design development, analysis, and sample size determination.
- Strong knowledge of ICH guidelines and other guidelines such as GCP, and 21 CFR Part 11 from different regulatory agencies including FDA, and EMEA.
- Experience in developing statistical analyses reports, and in conducting statistical analyses and reporting for various trial level deliverables including but not limited to blinded data reviews, interim analyses,
- Knowledge of coding dictionaries (WHO, COSTART, ICD-9, MedDRA) and clinical reporting processes.
- Knowledge of CDISC® related data models such as SDTM, and ADAM.
- Ability to work on multiple clinical protocols at the same time.
- Ability to balance conflicting priorities
- Ability to understand timelines and milestones affecting his or her work and communicating
- Excellent verbal and written communication skills
- Detail oriented, ability to multitask with strong prioritization, planning and organization skills
- Excellent team player

Technical Skills & Experience:

- Experience of statistical procedures and methodologies.
- Strong knowledge of statistical programming and ability to use various software systems like SAS, SPSS, and S-Plus. Ability to do statistical computing using R is a plus.
- Knowledge and ability to use various tools like J-Review and Spotfire for effective data queries and analysis.
- Ability to mine and model the clinical data as needed.
- Strong experience in various SAS software modules including SAS/STAT, and SAS/Graph.
- Thorough understanding of developing macros and SAS system.
- Thorough knowledge of design of experiments and statistical modeling. Thorough knowledge of analysis of various standard and non-standard safety domains. Knowledge of PK data modeling is a plus.
- Proficiency in Microsoft Office Applications