Director, Biostatistics

Summary Description

Responsible for supporting the planning, oversight and implementation of statistical analysis for clinical trials across a project as the statistical lead, spanning from the design and development of clinical trial documents and selection through the oversight of protocol implementation, data analysis and assembly of final study documents. Provides input to the design and development of documents for clinical studies, including protocols, case report forms, analysis plans, etc., and will participate in the selection of appropriate vendors or contractors for execution of the biostatistics and SAS programming elements of all clinical work within a project.

Key Responsibilities

- Leads the statistical strategy across a development program.
- Selects appropriate statistical methods for analysis of clinical study data. Liaises with product strategy teams to communicate biostatistics approach for development plans within a project
- Calculates sample sizes/power for proposed studies, for alternative designs, and evaluates the advantages/disadvantages and timelines for various scenarios
- Manages biostatistics vendors, contractors, and CROs
- Leads the study and/or project teams in the review and discussion of analysis plans
- Writes and/or approves all analysis plans, statistical sections of protocols and reports, statistical sections of abstracts, publications and presentations, and statistical requirements for data collection within a project
- Manages biostatistics and programming deliverables for CSRs and submission documents from CROs
- Key member of submissions team
- Responsible for interacting with Health Authority personnel on statistical questions

Experience & Education

- Master's Degree or higher in Statistics, Biostatistics, Mathematics, or closely related field
- Minimum of 12 years of experience in a drug-development environment. Minimum of 10 of those years directly in the pharmaceutical/biotech industry
- Knowledge of pharmaceutical and regulatory requirements, procedures, and policies
- Knowledge of GCP, ICH, and other Guidance documents and policies related to clinical trials operations requirements
- Proficiency in SAS and nQuery/EAST software packages
- Knowledge of CDISC requirements.
- Ability to oversee programming work performed by programming staff or vendors
- Strong verbal and written communication skills, strong interpersonal skills
- Ability to work well in a team environment
- Demonstrated high proficiency in project planning and management and proactively anticipate and identify complex issues and problems