Senior Director, Biometrics

Remote

Summary

Reporting to the Chief Medical Officer, the Senior Director, Biometrics will play a key role in Sierra Oncology's drug development programs and will manage all operational aspects of Biostatistics, Data Management and Statistical Programming within Sierra's drug development programs. This individual will provide leadership and strategic guidance on designing studies, selecting appropriate and innovative statistical methods, performing analyses, interpretation, and reporting of study results.

Responsibilities

- Participate in preparation of clinical and preclinical study designs and protocols, specifically coordinating, facilitating and constructing appropriate statistical sections of the protocol, statistical analysis plans and CRFs, database design and analysis.
- Implementation of protocol methodology and statistical plan to assure timely and accurate, complete and consistent analyses.
- Participate in preparation of the statistical section of all Clinical Study Reports (CSR) to support the development plan in a manner that fulfills all requirements for regulatory filings.
- Manage the design, development, selection, implementation and maintenance of in-house data management and statistical analysis capabilities.
- Manage and provide mentorship to a support team including statistical programmer(s) and data manager(s) as applicable
- Participate in strategic management meetings and decision-making.
- Participate in proactively formulating data-driven analytical strategies that successfully execute our core business of pharmaceutical development.
- Contribute as a member of the clinical and project teams,and serve as an internal resource to provide technical expertise for management, scientists, and other colleagues.
- Evaluate databases and statistical analysis programs and interact with IT groups to determine hardware/software compatibility.
- With guidance from the Chief Medical Officer and clinical operations group, deliver appropriate, accurate and understandable line listings and statistical tables, and preparation and review of statistical sections of study reports and submission reviews.
- Use validated SAS (or equivalent) macros, supervise or writes SAS code, develops program verification procedures and plans to provide thorough and detailed reviews of documentation and analysis output.
- Contribute to development of timelines and budgets within multidisciplinary project teams to ensure timely submissions aligned with our objectives.
- Develop and routinely review Biometrics SOP to ensure adequate processes are in place to manage quality work in line with regulations.

- Supervise review of CRFs to issue queries and clean data as required and direct database lock/unlock by following the guidelines established in the DMP and/or applicable SOPs and ensures archiving of the study databases and related.
- Participate in regulatory submission process (including INDs, CTAs, NDAs), and serve as statistical interface with the FDA for regulatory submissions and approvals and provide appropriate biostatistical updates to those documents.
- Ensure that all documents to be submitted to regulatory agencies are complete, statistically accurate, well organized and of high quality.
- Participate in analysis and review of data, and review, edit and contribute to the construction of clinical documents (study reports, publications and summaries) to ensure compliance with GCP and accurate presentation of data.
- Provide positive environment to facilitate interaction with less experienced personnel in order to communicate statistical concepts.
- Other related duties as assigned.

Qualifications and Requirements

- PhD in Biostatistics or Statistics with five plus years of pharmaceutical industry clinical development experience including support of product approvals and experience with clinical data management systems, or the equivalent combination of education and experience.
- Experience with strategic clinical trial planning and analyses that include experimental design, data analysis methodology, SAS programming, use of statistical software, statistical interpretation writing that are applicable to meet FDA and ICH guidelines.
- In-depth experience with all stages of data management from database setup up through final database lock.
- Good problem solving, decision making, leadership and communication skills.
- Ability to work independently and as a functional leader and participant in teams.
- Intermediate/Advanced knowledge of Microsoft 365 (Word, Excel, Outlook, PowerPoint) and advanced knowledge of Internet search engines and data sources.