Director, Biostatistics

Remote

Summary

Reporting to the VP of Biometrics, the Director, Biostatistics, will play a key role in Sierra Oncology’s drug development programs and will participate in operational aspects of Biostatistics and Statistical Programming within Sierra’s individual drug development programs.

This individual will work primarily in analyzing clinical trial data with contributions to study design as needed and appropriate. This work will include developing and implementing statistical analysis plans, performing pre-specified (if applicable) and exploratory/ad hoc analyses and providing statistical input to protocols, clinical study reports (CSR) and other Regulatory documents as well as for scientific presentations/manuscripts. They will perform statistical functions for submission related activities. To successfully execute this role, this individual must possess excellent statistical programming skills and be able to independently generate statistical analyses. The position will also participate in enhancing statistical expertise of the department and developing biometrics/biostatistics processes.

In carrying out their responsibilities, this individual will interface with Clinical Development, Data Management, Clinical Operations, Research, Medical Writing and other functions. This position will participate in managing and providing guidance to statistical programming vendors to ensure the quality of all deliverables and adherence to requirements/timeline.

Responsibilities

- Perform pre-specified (if applicable) and exploratory/ad hoc analyses of clinical trial data to answer questions for abstracts, posters, presentations, publications and regulatory submissions.
- Draft and review written summaries of investigations and analyses that are used in internal and external presentations.
- Maintain inventory of completed analyses and the associated code, in order to maintain control over an expanding pool of scientific and regulatory questions.
- Participate in the preparation of clinical and preclinical study designs and protocols, specifically coordinating, facilitating, and constructing appropriate statistical sections of protocols, statistical analysis plans, CRFs, database design and analysis.
- Implementation of protocol methodology and statistical plans to assure timely and accurate, complete and consistent analyses.
- Participate in preparation of the statistical section of CSRs to support the development plan in a manner that fulfills all requirements for regulatory filings.
- Contribute as a member of the clinical and project teams and serve as an internal resource to provide technical statistical expertise.
- Use validated SAS (or equivalent) macros, writes SAS code, develops program verification procedures and plans to provide thorough and detailed reviews of documentation and analysis output.
• Participate as needed in regulatory submission process (including INDs, CTAs, NDAs), and support Sierra’s statistical interface with the FDA for regulatory submissions and approvals and provide appropriate biostatistical updates to Regulatory 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.
• Other related duties as assigned.

Qualifications and Requirements
• A minimum of a Master’s Degree with 8 plus years of experience or a PhD in Statistics or related field with 5 plus years of experience in clinical trial data analysis is required.
• Excellent SAS programming skills including experience with CDISC SDTM and ADAM data sets; ability to write reusable SAS code.
• Fluency in R and experience building sophisticated graphics for use in data presentations are pluses
• Knowledge of Regulatory Guidances required
• Good verbal and written communication skills
• Excellent critical-thinking skills with respect to extracting information from data. Data mining experience a strong plus.
• Strong computer skills with regard to the Microsoft 365 platform of tools.
• Self-directed and independent worker but willing to work within a fast-paced and demanding team environment.
• Other important requirements include interdependent/analytic thinking skills, building strategic working relationships, and capability of making high-quality decisions.

How to Apply
To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.