Director/Sr Director Biostatistics

Synthorx is a biopharmaceutical company dedicated to delivering new biologic medicines to patients suffering from cancer and autoimmune disorders. Synthorx is applying a revolutionary synthetic biology technology based on an expanded DNA code to create designer protein-based medicines.
We are hiring a driven, resourceful, and collaborative Director/Senior Director, Biostatistics to join our team. The Director/Sr Director of Biostatistics will be responsible for providing technical leadership and biostatistical support to the Clinical Development research program through design and conduct of clinical studies; review and accuracy of clinical data; the evaluation, interpretation, and reporting of study results; and regulatory submissions to the FDA and other regulatory agencies.

Key Responsibilities

- Reviews or authors statistical analysis sections of protocols, statistical analysis plans (SAP), clinical study reports (CSR), regulatory documents or scientific publications, generates or reviews study randomization, sample size/power estimations
- For assigned clinical development projects, provides statistically sound scientific methodology regarding experimental design and data analysis input to meet project objectives and FDA (and other regulatory agencies) statistical and data requirements
- Authors or leads the development of all aspects of preparation and execution of SAP to ensure efficiency, accurate, timely and quality outputs
- Reviews case report forms (CRF) to ensure that protocol objectives are met and project standards are maintained
- Develops statistical programs or oversees their preparation as needed to perform pre-specified or ad-hoc analyses and prepare data displays
- Supplies statistical input for regulatory submissions and in response to FDA/EMA questions
- Assists with statistical and operational aspects pertaining to Data Monitoring Committees
- Performs and reports study results of appropriate statistical analyses, in collaboration with other relevant scientific disciplines where applicable, to provide appropriate interpretation of data and sound study conclusions
- Collaborates with the programming and data management functions to ensure data collection and reporting is done in conformance with ongoing practice and regulatory expectations
- Maintains currency with respect to FDA/EMA/ICH guidelines for statistical and clinical data analysis, data structure, and new developments in statistics and drug development
- Evaluates alternative or innovative methods of analyzing and interpreting data and evaluates implications for study design
- Assists company in the evaluation of Contract Research Organizations (CRO), specifically the biostatistics, statistical programming, and data management functional area
- Oversees statistical and programming deliverables by CRO (e.g., SAP, CDISC data, Define.xml, SDTM, ADaM)
- Assists the organization in identifying consultants or other external talent, where needed
- Assists in the development of SOPs and work procedures for biostatistics, statistical programming, and data management
- Mentor junior statisticians and statistical programmers

Required Qualifications

- M.S. in Statistics, Biostatistics, or Mathematics; PhD preferred
- 12+ years (M.S.) or 10+ years (Ph.D.) of progressive and relevant experience in pharmaceutical or biotechnology clinical trials
- Prior oncology experience is required.
- Significant experience in full-cycle drug development/pharma required; Experience participating in the commercialization of therapeutics is highly desirable
- Significant and demonstrated experience selecting/managing biostatistics CROs and vendors
- Technical knowledge of database structure, relevant statistical software such as SAS®, East®, and R
- Strong SAS® programming background including macro development and program validation
- Demonstrated experience leading change implementations using FDA/CHMP/ICH guidelines and Regulatory submission of datasets using CDISC, including development of SDTM and ADaM specifications
- Knowledge of pharmaceutical clinical development and ability to effectively apply technical principles, theories and concepts to clinical drug development
- Effective in communication and team collaboration
- Demonstrated ability to develop, communicate, negotiate and implement solutions to statistical issues and processes to yield more accuracy and greater productivity
- Project management and planning skills required; Knowledge of cross-functional department functions/roles
- Demonstrated ability to handle high volumes of work in a fluid, dynamic, stressful and fast-paced environment
- Demonstrated ability to work simultaneously on multiple projects, and to deliver high-quality work according to tight timelines
- Demonstrates excellent communication (verbal/written/presentation) skills
- Demonstrates sound judgment, facilitation and interpersonal skills
- Detail-oriented with effective problem-solving and troubleshooting skills
- Significant experience and understanding of medical terminology
- Significant experience using Microsoft Office Suite including Project, Excel, PowerPoint required; Experience with SharePoint or similar work management software/systems highly preferred
- Passion for science
- Potential for travel (US and International)