Director / Associate Director, Biostatistics
Job Code 509HY

Description

Fate Therapeutics is seeking a highly skilled and motivated statistician to serve as a statistical lead in our Biometrics Group. This individual will provide statistical leadership and technical expertise to Fate's clinical development programs. This position will also be responsible for providing oversight to biometric vendors to ensure timely and quality statistical deliverables. The successful candidate collaborates cross-functionally with Clinical Development, Clinical Operations, Clinical Translation, Regulatory Affairs, and Quality Assurance teams. The ideal candidate should have in-depth knowledge in advanced statistical methods and strong expertise in novel study designs of oncology and hematology-oncology clinical trials. This is a full-time position reporting to the Vice President, Biometrics and is located at our corporate headquarters in San Diego, CA or at our San Francisco Bay location.

Responsibilities:

- Develop and drive statistical strategy to clinical programs and ensure the statistical soundness of the overall strategy and appropriateness of proposed study designs
- Provide input to design options, outcome measures, endpoint assessment, and sample size/power calculations during protocol development
- Review and author statistical sections of protocols, clinical study reports (CSR), and regulatory documents
- Develop and author statistical analysis plans (SAP) for CSR and integrated summaries
- Utilize knowledge of industry standards for database and dataset design (CDISC: SDTM and ADaM)
- Collaborate with data management and programming functions to ensure optimal database design and build
- Support internal data review activities, e.g. Safety Assessment Committee, and external data review activities, e.g. independent data monitoring committees
- Provide input for regulatory submissions and responses to regulatory inquiries and represent Fate in interaction with Health Authorities
- Provide statistical guidance to biometric vendors and contracted personnel
- Research statistical methodologies and statistical issues pertaining to design of clinical trials
- Stay current with FDA/EMA/ICH guidelines for statistical and clinical data analysis, data structure, and new developments in statistics and drug development
- Contribute to the development of statistical SOPs and best practices
- Provide independent programming for complex statistical analyses and visualization
- Contribute to presentations at scientific meetings and publication in peer-reviewed journals as the primary statistical author
- Manage and mentor junior staff members as needed
- Take on other tasks as required

Qualifications

- PhD or MS in Biostatistics, Statistics or closely related field with a minimum of 10 years (Director) or 7 years (Associate Director) of progressive and relevant experience in pharmaceutical or biotech industry
- Track record of professional development with increasing levels of responsibility in the design and analysis of clinical trials
- Knowledge of GCP, ICH, CDISC and other pertinent regulatory guidance
- Strong SAS and R programming experience
- Advanced knowledge of statistical methods and innovative clinical trial design
- Ability to conduct independent research and resolve statistical methodological issues
- Demonstrated ability to manage competing priorities and deliver high-quality work under tight timelines
- Experience in managing junior members of staff
- Experience in authoring and contributing to technical documents such as Statistical Analysis Plans, Clinical Study Reports, manuscripts and abstracts
- Excellent communication skills
- Strong team player
- Experience of interacting with regulatory authorities highly desirable
- Oncology clinical trial experience strongly preferred
- Ability of managing CRO and external vendors
- Collaborative teamwork and interpersonal skills that demonstrate initiative and motivation

Working Conditions and Physical Requirements

- May require occasional evening and weekend work.
- Full-time onsite work at Company's headquarters in San Diego or in South San Francisco, California.
- Minimum 10% time traveling to clinical sites and clinical/professional meetings. May include international travel.

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and resume to: careers@fatetherapeutics.com and reference job code 509HY.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell

product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). The Company's pipeline also includes ProTmune™, a pharmacologically modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease in patients with hematologic malignancies undergoing allogeneic stem cell transplant. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.