Senior Statistical Programmer / Statistical Programmer, Biometrics
Job Code 614SC

Description

Fate's Statistical Programming group is currently seeking an experienced Statistical Programmer to be responsible for managing and supporting statistical programming deliverables for multiple clinical studies, as well as process improvement activities and department initiatives. This role is responsible for production and quality control of tables, listings, figures, and analysis datasets. The successful candidate will perform day-to-day data statistical programming according to ICH guidelines, regulatory requirements, and the company's standard operating procedures. This position reports to the Director, Statistical Programming and is located at our corporate headquarters in San Diego, California.

Primary Responsibilities:

- Work as a primary programmer or support lead programmer with statistical programming deliverables.
- Work collaboratively with different functions to meet project deliverables and timelines for statistical data analysis and reporting.
- Work with external vendor to ensure quality of deliverables. Independently check and validate programming deliverables from external vendor.
- Assist in the review of key study-related documents produced by other functions, e.g. SAP, case report form, data management plan, database specifications, EDC data structures and other clinical documents.
- Produce tables, listings and figures for study specific as well as any ad hoc requests using Base SAS, SAS Macros, SAS/STAT, SAS/Graph, SAS/SQL and SAS/ODS.
- Assess the quality and consistency of analysis data and perform cross-study analyses.
- Uses internal macros or writes SAS® macros to automate study deliverables.
- Develop analysis specification & programs and help with validation activities.
- Identify potential issues in study documentation and propose solutions.
- Contribute to strategic initiatives.

Requirements

- BS / MS degree in Computer Sciences, Mathematics, Life Sciences or other relevant scientific degree with 3 or more years of experience in the pharmaceutical/biotechnology industry.
- Knowledgeable about working with clinical databases such as Medidata RAVE, Oracle, or other.
- Ability to create and present PowerPoint slides from data for internal and external stakeholders, including clinical monitors, statisticians, data managers and medical writers.
- In-depth knowledge of FDA/ICH guidelines and industry/technology standard practices required.
- Detailed knowledge and experience in clinical study design, CRF design, central laboratories, programming databases, query resolution, data validation.
- Knowledge of regulatory requirements for dataset submissions and relevant hands-on experience.
- Good understanding of clinical data and pharmaceutical development.
- Demonstrated proficiency in using SAS to produce derived analysis datasets and produce tables, figures and listings (TFLs).
- Understanding of clinical data structures, relational database structures, and data exchange with alternate data formats.

- Demonstrated knowledge in the handling and processing of upstream data, e.g., multiple data forms, workflow, EDC, SDTM.
- Demonstrated knowledge in providing outputs to meet downstream requirements, e.g., ADaM, Data Definition Table, e-submission.
- Good knowledge of statistical terminology, clinical tests, medical terminology, and protocol designs.
- Experience in oncology clinical trials preferred.
- Experience with complex graphing techniques desired.
- Knowledge in other programming languages and software packages such as R, Python, and Spotfire desired.
- Ability to manage multiple and diverse issues and the ability to problem solve.
- Ability to work collaboratively with CRO and external vendors.
- Collaborative teamwork and interpersonal skills that demonstrate initiative and motivation.
- Exceptional interpersonal skills and problem-solving capabilities.
- Flexible, team-oriented, and results driven.
- Excellent oral and written communication and presentation skills.

Working Conditions and Physical Requirements
- Onsite work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work may be necessary
- Ability to travel up to 10% of time

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 614SC.

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). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.