Director, Clinical Data Management
Job code 207CW

Description

Fate's Biometrics team is currently seeking a skilled and motivated data management professional to contribute to and manage the database development and ongoing quality of the data, ensuring operational strategy and implementation are compliant for the Company's clinical trials. The ideal candidate will have advanced knowledge of clinical trial processes and be proficient in all aspects of data management from study start-up to study close-out, have experience in the oversight of CROs and 3rd party vendors; in addition, have knowledge of implementing CDISC CDASH CRF Standards and CDISC SDTM/ADaM datasets, have experience in designing and validating clinical trial databases. This is a full-time position reporting to the Chief Medical Officer and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Provide data management expertise related to CRF design, database build, and data cleaning for multiple clinical development programs to ensure clinical data of the highest quality
- Manage data management deliverables in coordination with internal stakeholders and external vendors
- Provide oversight to external data management vendors and manage data transfers to/from such vendors
- Coordinate cross-functional input into optimal database design
- Work closely with medical, clinical operations and biostatistics colleagues on the resolution of issues with clinical data
- Author and review applicable sections of data management related documents such as case report forms, data management plans, data transfer specifications, coding standards, manual review plans, line listing review plans, data validation plans, and clinical study reports and any other related documents
- Assist in the development of innovative and robust methods for ongoing data review as well as pharmacovigilance monitoring
- Oversee the development of and implement data management standards for the department
- Provide data review listings and other tools on an ongoing basis to assist in internal data review
- Management and mentorship of junior members of staff
- Contributions to other tasks as required

Qualifications

- 10+ years of direct data management experience in drug/device development, or equivalent experience

- Track record of professional development with increasing levels of responsibility in the design and analysis of clinical trial data
- Strong knowledge of GCP, ICH, CDASH, CDISC and other pertinent regulatory guidance
- Willingness to develop/learn innovative data management methodology
- Experience in managing junior members of staff
- Excellent communication skills
- Strong team player
- Ability to manage multiple competing priorities
- Oncology clinical trial experience strongly preferred

Working Conditions and Physical Requirements

- 100% on-site work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work will be required
- Ability to travel domestically and internationally up to 20% of the 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 207CW.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for cancer and immune disorders. The Company is pioneering the development of off-the-shelf cell therapies using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline is comprised of FATE-NK100, a donor-derived natural killer (NK) cell cancer immunotherapy that is currently being evaluated in three Phase 1 clinical trials, as well as iPSC-derived NK cell and T-cell immunotherapies, with a focus on developing augmented cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-specific antigens. The Company's immuno-regulatory pipeline includes ProTmune™, a next-generation donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease, and a myeloid-derived suppressor cell immunotherapy for promoting immune tolerance in patients with immune disorders. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.