



Senior Clinical Trial Manager
Job Code 191SW

Description

Fate's Clinical Operations team is currently seeking a talented and motivated clinical operations professional to support our clinical trials. The successful candidate must have experience managing Phase I-III trials and a good knowledge of clinical operations, GCP and FDA regulatory environment. Oncology trial experience preferred. This is a full-time position reporting to the Executive Director, Clinical Operations, and is located at our Company's headquarters in San Diego, California.

Responsibilities:

- Study management and GCP vendor oversight in day to day clinical operations. May be responsible for multiple clinical projects in various stages of development.
- Oversee study subject enrollment and monitoring activities at participating clinical sites.
- Designated team leader responsible for coordination of project activities and project goals.
- Responsible for Trial Master File implementation and maintenance.
- Develop study documents and tools including study protocols, consent forms, project plans, budgets, logs, templates, newsletters, and other, as needed.
- Develop SOPs and best practices and facilitate their implementation.
- Provide study status updates and reports.
- Conduct ongoing study data reviews and data cleaning activities.
- Interact efficiently and professionally with participating study sites' staff, internal staff, and other departments to ensure smooth study conduct.
- Perform and/or oversee monitors delegated to perform tasks related to site qualification, initiation, interim monitoring, and close-out visits, as needed.
- Develop and deliver study training to investigators, site staff, and internal staff on select study processes.
- Develop processes and provide oversight of study supplies management.
- Conduct internal meetings for assigned clinical trial(s) and prepare minutes, as necessary.
- Conduct external meetings (e.g., Investigator Meetings), conferences and events.
- Interface with representatives from other key functional groups including research and development, regulatory, quality, and legal as appropriate.

Qualifications

- B.S. degree with minimum 8 to 10 years clinical experience in biotech, pharmaceutical, and/or CRO environment.
- Good knowledge of clinical operations and experience with clinical study conduct from start-up through close-out.
- Oncology experience preferred.
- Working knowledge of relevant GCPs and FDA regulations.
- Experience operating in a matrix organization.
- Ability to work effectively with minimal supervision and multi-task activities to effectively manage deliverables across all trials.
- Strong team orientation, with excellent written and oral communication skills.



Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- Full-time onsite work at Company's headquarters in San Diego
- Minimum 10% time traveling to clinical sites and clinical/professional meetings

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 191SW.

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. This platform uniquely enables the single-cell selection of a precisely engineered iPSC clone and the subsequent creation and maintenance of a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for consistently and repeatedly manufacturing homogeneous cell products in quantities that support the treatment of many thousands of patients in an off-the-shelf manner. 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.