Clinical Trial Manager
Job Code 528JT

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. The CTM is an important member of the clinical operations team, supporting the successful execution of clinical trials. This is a full-time position reporting to the Director / Associate Director, Clinical Operations, and is located at our Company's headquarters in San Diego, California or in South San Francisco, California.

Responsibilities:

- Manage the day-to-day components of a clinical trial under the direction of a Senior CTM and/or Clinical Program Manager.
- Ensure assigned deliverables are completed on time, within budget and in a highly dynamic and complex environment in accordance with appropriate quality standards including ICH/GCP requirements and Fate SOP.
- Support the identification, evaluation, selection and oversight of clinical trial sites. Partner efficiently, effectively, and professionally with participating sites to ensure smooth study conduct.
- Support the implementation of assigned operational activities to ensure efficient study enrollment and high-quality monitoring activities at clinical study sites.
- Assist with invoice review and study budget tracking.
- Support implementation and oversight of Trial Master File for inspection readiness.
- Assist with the development of study documents and tools, including study protocols, consent forms, project plans budgets, logs, templates, newsletters and other documents, as needed.
- Provide input to study updates for senior management, inclusive of study risks and issues for assigned activities. Assist with internal and external meetings for assigned clinical trial(s), including Investigator Meetings, conferences, events and study management team meetings.
- Support the ongoing study data reviews and data cleaning activities.
- May assist with study vendor selection and oversight for assigned vendors.
- Assist with activities related to site identification, qualification, selection, initiation, interim monitoring and close out activities.
- Assist with development and delivery of study training to investigators, site staff, and internal staff on select study processes.
- Support the development and complete the delivery of study trainings to investigators, site staff and internal staff on study processes. Participate in and support the follow up of internal process audits, vendor and study site quality audits as well as regulatory inspections.

Qualifications

- B.S. degree with a minimum of 3 years of experience supporting clinical trials in biotech, pharmaceutical, and/or CRO environment.
- Good knowledge of clinical operations and experience with clinical study conduct.
- Oncology experience required (solid tumor, lymphoma or multiple myeloma experience preferred).

- Working knowledge of relevant GCPs and FDA regulations.
- Experience operating in a matrix organization.
- Ability to work effectively with supervision and multi-task activities to effectively manage deliverables.
- Effective collaboration and strong written and oral communication skills.

Working Conditions and Physical Requirements

- Strong collaboration and team orientation, with strong written and oral communication skills.
- 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.

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 528JT.

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.