Clinical Trial Manager II
Job Code 529JT

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 requirements. The CTM II is an important member of the clinical operations team, leading 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 all components of clinical trial, leading a cross-functional study team under the direction of the disease area lead or Clinical Program Manager (CPM). The assigned trial(s) may be of low- to moderate complexity or risk. May manage assigned components of high complexity or high risk, global, and/or pivotal trials under the direction of a Sr. CTM or CPM.
- Ensure clinical trial activities 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.
- Lead the identification, evaluation, selection and oversight of clinical trial sites. Partner efficiently, effectively, and professionally with participating study sites to ensure smooth study conduct.
- Implement operational plans to ensure efficient study enrollment and high-quality monitoring activities at clinical sites.
- Review invoices and track study budget to forecast, working closely with finance and clinical business operations.
- Responsible for implementation and oversight of Trial Master File for inspection readiness.
- Support the development of study documents and tools, including study protocols, consent forms, project plans budgets, logs, templates, newsletters and other documents, as needed.
- Provide study updates, inclusive of study risks and issues as well as and relevant reports to senior leadership.
- Lead internal and external meetings for assigned clinical trial(s), including Investigator Meetings, conferences, events and study management meetings.
- Responsible for ongoing study data reviews and data cleaning activities.
- Lead study vendor selection, qualification, and oversight activities.
- Provide oversight of CRAs and activities related to site identification, qualification, selection, initiation, interim monitoring and close out activities.
- Manage trial-level quality risk management
- Oversee of study supplies management.
- Support the development and complete the delivery of study trainings to investigators, site staff and internal staff on study processes.
- Participate in the preparation and 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 5 years of experience managing clinical trials in biotech, pharmaceutical, and/or CRO environment.
- Strong knowledge of clinical operations and experience with clinical study conduct from start-up through close-out, with global trials or CRO management experience preferred.
- Solid tumor, lymphoma or multiple myeloma experience required.
- Immunotherapy or cellular therapy 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.
- Ability to lead a cross functional study team
- Strong collaboration and team orientation, with 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 529JT.

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.