Senior Clinical Trial Manager
Job Code 501JT

Description

Fate's Clinical Operations team is currently seeking a talented and motivated clinical operation professional to support our clinical trials. The successful candidate must have experience managing Phase I-III oncology trials and a good knowledge of clinical operations, ICH/GCP and FDA regulatory requirements. The Senior Clinical Trial Manager (Sr. CTM) is a key member of the clinical operations team, leading the successful execution of clinical trials. This position contributes to and supports the Fate's research and development efforts to develop next-generation cellular immunotherapies for cancer and immune disorders. 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:

- Independently manage all components of a clinical trial, leading a cross-functional study management team. The assigned clinical trial may be of high complexity or high risk.
- Ensure clinical trial activities and deliverables are completed on-time, within budget, and in a highly dynamic and complex environment in accordance with appropriate quality standards including GCP/ICH requirements and Fate SOPs.
- 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 strategic operational activities to ensure efficient study enrollment and high-quality monitoring activities at participating clinical sites.
- Review invoices and track study budget according to the forecast working closely with finance and clinical business operations.
- Manage multiple clinical study vendors with oversight of activities.
- Responsible for implementation and oversight of Trial Master File for inspection readiness.
- Develop study documents and tools including study protocols, consent forms, project plans, budgets, logs, templates, newsletters, and other, as needed.
- Provide study status updates and reports to senior management.
- Lead ongoing study data reviews and data cleaning activities.
- Provide oversight of CRAs assigned to clinical trials and provide oversight of activities 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.
- Participate in the preparation and follow-up of internal process audits, vendor, and study site quality audits, as well as regulatory authority inspections.
- Conduct internal meetings for assigned clinical trial(s)
- Conduct external meetings (e.g., Investigator Meetings), conferences and events.

- Participate in RFP and vendor selection process working closely with Clinical Business Operations.
- Train and mentor new clinical trial staff with appropriate delegation and may be responsible for dotted-line management of team members.
- Escalate study issues/risks in a timely manner with solid communication skills.
- May develop SOPs and best practices and facilitate their implementation.

Qualifications

- B.S. degree with minimum 8 years of experience managing clinical trials in biotech, pharmaceutical, and/or CRO environment.
- Strong leadership, effective decision making, and problem-solving skills required.
- Strong knowledge of and strategic clinical operations. Strong experience with clinical study conduct from start-up through close-out, with global trial and CRO management experience highly preferred.
- Solid tumor, lymphoma or multiple myeloma experience required.
- Immunotherapy or cellular therapy experience highly 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 or in South San Francisco, California.
- Minimum 10% time traveling to clinical sites and clinical/professional meetings. May include international travel.

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 501JT.

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). The Company's pipeline also includes ProTmune™, a pharmacologically modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease in patients with hematologic malignancies undergoing allogeneic stem cell transplant. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.