Senior Director / Director, Clinical Trial Operations & Monitoring
Job Code 590LK

Description

Fate Therapeutics is seeking a Senior Director or Director, Clinical Trial Operations and Monitoring to provide management and oversight of Clinical Trial Associates (CTA), site monitoring, and specialized functions within Clinical Operations to ensure timely and appropriate management of study documentation, logistics, and consistent use of clinical systems. This role will work closely with other members of the clinical operations team and perform monitoring oversight visits and serves as the functional business owner for clinical operations systems. The successful candidate will work closely with cross functional teams including clinical development functions, legal, finance, regulatory affairs, quality assurance, and IT. This is a full-time position located at our corporate headquarters in San Diego, CA reporting to the VP, Clinical Development Operations.

Responsibilities

- Lead Clinical Trial Operations and Monitoring groups to provide continuous support activities for all FATE clinical trials.
- Recruit, manage, mentor, train and develop CTA, CRA and specialized Clinical Operations trial support team members including goal setting and development plans, provide performance feedback, and conduct performance evaluations.
- Partner with Clinical Operations to ensure the study management teams are sufficiently staffed and properly trained and equipped.
- Forecast CRA & CTA resourcing needs for all clinical trials.
- Manage functional service provider (FSP) and contractor CRAs; act as line-manager for all CRAs, as applicable.
- Partner with stakeholders to identify, manage, escalate, and resolve issues related to team performance.
- Oversee monitoring activities and perform regular monitoring oversight visits with CRAs.
- Periodically review monitoring visit reports, action items, and protocol deviations to ensure CRAs are performing at a high-quality level; identify and address trends as appropriate.
- Develop and monitor key performance indicators (KPIs) and conducts analysis to identify root causes for issues and recommends process improvements.
- Lead the standardization of monitoring processes and activities, including partnering with the study management team, to determine the best approach to risk-based monitoring.
- Act as subject matter expert (SME) / functional business owner for clinical operations systems. Partner with Clinical Systems Operations to optimize usage of selected systems.
- Partner cross-functionally to support inspection and audit readiness activities, support system requirements gathering and user guide development, and development and implementation of relevant trainings, processes and procedures including assigned Standard Operating Procedures (SOPs) with emphasis on CTA and CRA activities.
- Evaluates emerging trends, technologies, and best practices and provide recommendations and direction on strategic roadmaps.

Qualifications

- BS / BA in a relevant scientific discipline; advanced degree preferred
- Minimum of 10 years of experience in clinical operations leadership role in a biotech / pharmaceutical company or clinical research organization (CRO); small company experience preferred
- At least 6 years clinical monitoring and monitoring oversight experience
- Broad experience and knowledge of clinical drug development
- Experience supervising and developing direct reports
- Experience working with CRO / FSP partners and clinical trial sites supporting global clinical trials

- Extensive experience with CTMS and eTMF maintenance, Veeva Vault experience preferred
- Experience participating in a Regulatory audit preferred, particularly as it pertains to the eTMF
- Strong communication skills with the ability to create clear directives
- Excellent verbal, written, and interpersonal skills
- Extensive knowledge and understanding of FDA, EMEA, ICH, GCPs governing clinical trials conduct
- Excellent team player; willingness and ability to fill functional gaps in a growing organization
- Comfortable multi-tasking in a fast-paced small company environment and able to adjust workload based upon changing priorities
- Must have strong organization skills and the ability to operate both cross-functionally and independently, and be comfortable interacting with investigational sites
- Strong presentation skills
- Preference to energetic, dynamic candidates with a desire to think "outside the box"

Working Conditions and Physical Requirements

- Position is based on-site at corporate headquarters in San Diego, CA
- Willingness to travel as needed, up to 40%
- Occasional evening and weekend work will be required

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 590LK.

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.