Senior Clinical Trial Associate / Clinical Trial Associate
Job Code 427LS

Description

Fate's clinical operations group is seeking a motivated and talented individual to support development and management of an electronic trial master file system (Veeva) and assist our clinical trial managers with administrative and project-specific support related to the conduct of clinical studies. The successful candidate will assure adherence to protocol(s) and GCP/ICH guidelines and applicable regulations. The ideal candidate will be familiar with phase I-IV protocols and have hands-on experience in developing and maintaining electronic clinical trial management systems. Candidates must thrive in a fast-paced team environment. Excellent communication, organizational abilities, and independent problem-solving skills are a must. This is a full-time position reporting to the Associate Director, Clinical Trial Operations and is located at our company's headquarters in San Diego, California.

Responsibilities:

- Day to day management of the electronic clinical trial management file system, Veeva eTMF Vault
- Assist with the evaluation, development and implementation processes in Veeva eTMF
- Initiate, manage or assist with training on Veeva eTMF or document control processes
- Proactively maintain an understanding of regulations and best practices for TMFs
- Interact and follow-up with clinical trial sites in support of the CTM and CRAs
- Assist with collection of study related documents in collaboration with the clinical research associates
- Assist study teams with all aspects of clinical trials (start-up to closeout)
- Prepare and distribute regulatory binders, study reference binders, and other study supplies to sites
- Attend study team meetings and assist with meeting agendas and meeting minutes
- Assist in the development and review of clinical documents (e.g., protocols, informed consent forms, case report forms, monitoring plans, study tools, clinical study reports)
- Assist clinical operations staff in planning and logistics for meetings including investigator meetings, study team meetings, and meetings with CROs and other vendors
- Provide administrative support to clinical study teams
- Assist with timeline tracking and maintenance

Qualifications

- BS/RN degree or equivalent in a relevant scientific discipline
- Ideal candidate will have 1 or more of prior hands on experience managing electronic trial master file and clinical trial management systems, preferably in the biotechnology or pharmaceutical industry that includes work on early stage oncology trials
- Hands on experience with Veeva Vault Clinical Suite preferred
- Good communication skills and professional demeanor; ability to work in a team environment with medical personnel, clinical monitors, statisticians, data managers, medical writers, and internal cross-functional team members
- Working knowledge of FDA/ICH guidelines and industry/technology standard practices including Good Clinical Practices; trial initiation and management practices and procedures

- Experience working in clinical trial databases
- Understanding of clinical data and pharmaceutical development
- Ability to manage multiple and diverse issues

Working Conditions and Physical Requirements

- May require occasional evening and weekend work.
- Full-time onsite work at company's headquarters in San Diego.

For consideration send cover letter and resume to: careers@fatetherapeutics.com and reference job code 427LS.

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 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 product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include 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, 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.