In-House Clinical Research Associate
176DL

Description

Fate's clinical operations group is seeking a motivated and talented individual to support development and management of an electronic trial master file and clinical trial management system and assist our clinical trial managers with in-house co-monitoring activities. 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 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 Senior Manager, Clinical Operations, and is located at our Company's headquarters in San Diego, California.

Responsibilities:

- Day to day management of Company's electronic clinical management system in Veeva Vault.
- Support in-house monitoring tasks, including coordinating activities both internally and at clinical sites to ensure compliance for the conduct of clinical trials.
- Follow up with clinical operations staff and cross-functional team members, including regulatory, quality, and clinical research, to assure due diligence and tracking of all clinical documents.
- Interact with clinical sites and ensure both the Investigator file and trial master file are complete and current.
- Conduct co-monitoring and booster visits with other Fate and contract research organization (CRO) clinical research associates as needed.
- Assist clinical operations staff and communicate with the sites regarding study-specific issues.
- Problem-solve clinical research-related issues.
- Assis in the development and review of clinical documents including protocols/amendments/informed consent forms/case report forms/monitoring plans/investigator brochures/clinical study reports/annotated monitoring reports/study tools.
- Participate in vendor oversight activities, such as generation and/or distribution of study specific documents and tools.
- Assist clinical operations staff in training of CROs, vendors, investigators and coordinators on clinical study requirements.
- Coordinate drug/product supplies, laboratory supplies, and other study material needs with the clinical sites.

- Assist clinical operations staff in planning and logistics for meetings including investigator meetings, study team meetings, and meetings with CROs and other vendors.

Qualifications

- BS/RN degree or equivalent in a relevant scientific discipline.
- Minimum 2 years 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; ability to work in a team environment with medical personnel, clinical monitors, statisticians, data managers, medical writers, and internal cross-functional team members.
- In-depth knowledge of FDA/ICH guidelines and industry/technology standard practices including Good Clinical Practices; trial initiation and management practices and procedures.
- Detailed knowledge and experience in clinical study design, CRF design and review, central laboratories, clinical trial databases.
- Good 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.
- May require some travel for clinical programs 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.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cell lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.