



Clinical Research Associate II (In-House), Clinical Development Job Code 42LW

Company Overview

Fate Therapeutics is an innovative biotechnology company developing novel stem cell modulators (SCMs), biologic or small molecule compounds that guide cell fate, to treat patients with very few therapeutic options. Fate Therapeutics' lead clinical candidate, ProHema, consists of pharmacologically-enhanced hematopoietic stem cells (HSCs) designed to improve HSC support during the normal course of a stem cell transplant for the treatment of patients with hematologic malignancies. The Company is also advancing a robust pipeline of human recombinant proteins, each with novel mechanisms of action, for skeletal muscle, beta-islet cell, and post-ischemic tissue regeneration. Fate Therapeutics also applies its award-winning, proprietary, induced pluripotent stem cell (iPSC) technology to offer a highly efficient platform to recapitulate human physiology for commercial scale drug discovery and therapeutic use. With support from the U.S. Army, Fate Therapeutics is also investigating therapeutic intervention strategies to regenerate cells within the inner ear that are responsible for hearing. Fate Therapeutics is headquartered in San Diego, CA, with a subsidiary in Ottawa, Canada.

Description

Fate Therapeutics' clinical operations group is seeking a motivated and talented individual to monitor clinical trials at investigative clinical sites and assure adherence to the protocol(s) and GCP/ICH guidelines and applicable regulations. The successful candidate will oversee the progress of early phase protocols and ensure that studies are on track for meeting various timelines. The ideal candidate will have relevant industry experience monitoring early development oncology trials. Candidates must thrive in a fast-paced team environment. Excellent communication, organizational abilities, and problem-solving skills are a must.

Responsibilities

The ideal candidate will perform a range of activities focused on monitoring clinical trials. Activities will include:

- Manage internal and external monitoring and administrative aspects of phase I/II multi-center trial from study initiation to completion/close-out.
- Travel to clinical sites, and arrange own schedule and travel arrangements for qualification, initiation, routine and study close-out monitoring visits.
- Responsible for knowing the status of CRFs in-house and outstanding queries.
- Review site and study regulatory documentation.
- Communicate with the sites regarding study specific issues.
- Problem-solve routine clinical research-related issues.
- Contribute to development of RFPs.
- Contribute to preparation and review of clinical documents (protocol amendments/informed consents/case report forms/monitoring plans/investigator brochures/clinical study reports).
- Participate in vendor oversight activities, such as generation and/or distribution of study specific documents and tools.



- May train CROs, vendors, investigators and coordinators on clinical study requirements.
- Coordinate drug/product supplies, laboratory supplies, and other study material needs with the clinical sites.
- Support planning and logistics for meetings including investigator meetings, study team meetings, and meetings with CROs and other vendors.
- Anticipate needs to meet the objectives of the clinical research projects and responsible for knowing the overall status of projects and providing updates.
- Assist in preparation of study budget for protocols.

Candidate Requirements

- B.S. in Life Science, Health Care or Biological Sciences
- At least 2 years of clinical operations experience in the biotechnology or pharmaceutical industry that includes work on early development oncology trials
- Working knowledge of Good Clinical Practices; ICH guidelines; trial initiation and management practices and procedures
- Knowledge of pharmaceutical industry Standard Operating Procedures
- Experience with preparing study initiation documents
- Proficiency in basic monitoring skills including interpretation of clinical study protocols, and reviewing case report forms for accurate data completion
- Familiarity in reviewing source documents at clinical sites and experience with preparing Patient Informed Consents, review and documentation at the clinical sites
- Experience working with CROs, and data management, central lab and IVRS vendors
- Strong organizational, analytical, and problem-solving skills
- Strong interpersonal skills, with excellent written and oral communication skills

Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- Requires travel for clinical programs and scientific/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 curriculum vitae to: careers@fatetherapeutics.com and reference job 42LW.