



**Clinical Research Assistant/ Clinical Research Associate I,
Clinical Operations, Job Code 43LW**

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 perform in-house monitoring tasks, including coordinating GCP activities both internally and at clinical sites to ensure compliance for the conduct of clinical trials and to follow up with the monitoring staff, other departments, and clinical sites to assure due diligence. The ideal candidate will have relevant industry experience monitoring 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:

- Responsible for submission and tracking of clinical operations regulatory documents, follow up with clinical sites, work with internal and contract CRA's, and CRO personnel to assure receipt of all outstanding regulatory documents.
- Develop and maintain tracking systems for all documents related to clinical trials for the clinical operations group and transfer all required documents to a central filing system.
- Assist CRAs including copying files, ordering monitoring supplies and manage onsite supplies, making sure onsite and clinical sites stocked with lab supplies, CRF's and other applicable documents and materials.
- Perform requests for drug shipments and tracking to and from clinical sites.
- Compile site study binders, CRF instruction manuals, and other documents requiring assembly.
- Provide project related support for clinical operations group.
- Process and track payments to vendors and study sites as appropriate.
- Generate, finalize and distribute study team agendas and meeting minutes.
- May co-monitor sites with CRAs.



Candidate Requirements

- B.S. in Life Science, Health Care or Biological Sciences plus a minimum of 1 year experience in the pharmaceutical or biotech industry specifically in clinical operations
- Familiarity with Good Clinical Practices and pharmaceutical industry Standard Operating Procedures
- Familiarity with clinical documents including but not limited to study protocols, CRFs, regulatory documents, investigator file, visit reports
- Excellent organizational skills, including ability to manage several projects concurrently
- Ability to prioritize and manage workload to meet clinical operations and corporate projects related timelines
- Self-motivated, independent, and ability to follow through on projects with minimal supervision
- Ability and confidence to make routine decisions
- Excellent computer skills and attention to detail
- Strong interpersonal skills, with excellent written and oral communication skills

Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- May require 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 43LW.