Clinical Scientist, Clinical Development
Job Code 417JC

Position Description

Fate Therapeutics is seeking an experienced, independent and highly motivated clinical scientist professional. The successful candidate will be a member of the clinical development team, working closely with both the clinical and research groups (medical monitor, statistician, regulatory, translational research) to support and deliver clinical development strategies. The position contributes to the trial development strategy and execution, assisting with protocol development, study design and clinical study supporting functions. The successful candidate will be familiar with current approaches regarding oncology treatment modalities, drug mechanism of action, approaches to drug development, and regulatory and operational requirements. The ideal candidate should have experience in solid tumor oncology, with experience in the design and conduct of clinical studies in this therapeutic area. Experience with cellular therapies is desirable. The position reports to the VP, Clinical Development and is based at the Company's corporate headquarters in San Diego, California or remotely from the San Francisco, California area.

Major Responsibilities

- Analyze and interpret study data from individual study and translate study level clinical data across the program of studies for a particular compound ensuring that all studies are conducted with the highest level of ethical and safety standards and are in compliance with GCP and all regulatory policies.

- Work with Medical Director(s) to create key strategic documents including clinical development plans, protocol synopses and full protocols for defined product(s), in addition to amendments and related documents.

- Contribute to the development of clinical sections of regulatory documents including Investigators' Brochures, briefing books, safety updates, IND/NDA submission documents, study protocols, informed consents, eCRFs, statistical analysis plans, regulatory approval submissions, serious and non-serious adverse event evaluation, and supporting responses to Health Authorities questions.

- Maintain familiarity with standards of practice in the relevant therapeutic areas in order to contribute to strategic discussion and decision-making for the program.

- Contribute to data activities including data cleaning and database locking; review of safety fields for reconciliation (if needed), working with data group to reconcile SAE events (as needed); review of medical coding of adverse events, laboratory data and concomitant medications for accuracy, coherence, consistency, and trends; review of data tables, listings, and figures; review and / or writing portions of final clinical study report.

- Develop effective working relationship with key investigators in assigned programs to optimize scientific quality / innovation of clinical study design, execution, reporting and publication.

- Contribute to trial-related advisory boards, investigators meetings, DMC and protocol training meetings.

- Coordinate the real time availability of quality clinical trial data, including safety, efficacy, pharmacokinetic and biomarker data, to provide consolidated information for Senior Management.

- Assist in forecasting trial resource needs (external costs).

Requirements

- MS, RN, PhD, or PharmD with a minimum 5 years technical, operational and managerial experience in planning, executing, reporting, and publishing clinical studies in a biotech, pharmaceutical, or CRO environment.
- 5+ years of experience in the design and conduct of solid tumor oncology clinical trials is desirable.
- Experience in novel combinations and innovative designs for early phase studies. Phase 3 trial experience is a strong plus.
- A hands-on, independent and driven individual who can take charge of the work and is willing to contribute at different levels; e.g., engage with investigators, KOLs, etc. one-on-one as well as dig into the data.
- Ability to produce written scientific communications with clarity, accuracy and rigor.
- Experience with U.S. and European regulatory authorities and submissions is desirable.
- Experience or exposure to the development of cell therapies is desirable.
- Self-motivation, good judgment, strong follow up, organizational, analytical, and problem-solving skills; capable of identifying risks; creative and innovative thinker.
- Ability to work, lead and motivate a cross-functional matrix team.
- Excellent written and oral communication skills. Ability to communicate effectively through formal presentation and through informal scientific discussion with credibility, accuracy, and confidence with internal and external stakeholders and experts.

Working Conditions and Physical Requirements

- Travel between office locations as required
- Occasional travel to meetings and conferences as required
- 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 curriculum vitae to: careers@fatetherapeutics.com and reference job 417JC.

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.