Director, Clinical Operations
(Multiple Myeloma or B-cell Franchise)
Job Code 422SW

Description

Fate's Clinical Operations team is currently seeking a hands-on talented and motivated clinical operations professional to lead the clinical program for our multiple myeloma or B-cell franchises. The successful candidate must have extensive experience managing early and late-stage clinical trials, experience managing direct reports, and in-depth knowledge of clinical operations, GCP/ICH and FDA and international regulations. The position provides leadership and guidance to clinical operations staff and establishes and maintains relationships with CROs and vendors supporting clinical operations deliverables. This position collaborates cross-functionally with clinical development, clinical operations, regulatory affairs, and quality assurance teams. Extensive multiple myeloma trial experience preferred. This is a full-time position reporting to the Executive Director, Clinical Operations, and is located at either our Company's headquarters in San Diego, CA or in South San Francisco, CA.

Responsibilities:

- Develop the operational strategy and oversee successful execution of clinical studies within the franchise therapeutic area.
- Accountable for meeting all operational deliverables in accordance with time, cost and quality commitments. Maintains an overview of status, risks, and proactively communicates progress, issues or changes that may impact timelines and costs of the program to all stakeholders including the franchise team. Maintains internal consistency across studies within a program.
- Provide disease area expertise and input to Clinical Operations and anticipate changes in the disease landscape (e.g. standards of care) and regulations that impact operational strategies.
- Provide leadership, guidance, and manage the performance and development of direct reports; administer performance programs in accordance with policies; and ensure the development of potential succession candidates.
- Recruit and hire Clinical Operations staff, as well as oversee their work to ensure all department goals, deliverables and objectives are met.
- Ensure that employees are appropriately trained, developed and coached to comply with company policies, regulations, and ICH GCP.
  Responsible for leading strategic initiatives and process development in support of the Fate Clinical Development Operations department and clinical trials.
- Provide program and study status updates to the executive leadership team.
- Partner with representatives from other internal key functional groups including research and development, regulatory, quality, and legal as appropriate.
- Oversee strategic relationships with vendors and key clinical investigators.
- Ensure risk-based approach to study management. Serve as a point of escalation, root cause analysis and corrective action for clinical studies and vendors.

- Responsible for reporting on key performance indicators for therapeutic area and related actionable follow-up.
- Ensure consistency and approach with study documents, including study protocols, consent forms, project plans, budgets, and others, as needed.
- Serve as back-up to study CTMs and enable study continuity in the case of resourcing changes.
- Contribute to SOPs and processes and facilitate their implementation.
- Oversee enrollment and milestone projections to enable clinical supply projections and cross functional planning.
- Conduct external meetings (e.g., Investigator Meetings), conferences and events.

Qualifications

- B.A./B.S. degree, preferably in the life sciences; advance degree preferred.
- 10+ years in industry experience in all phases of clinical trial management and drug development and filing INDs and NDAs/BLAs.
- Expertise in disease area.
- Proven expertise managing individuals, teams, and functional groups.
- Experience managing clinical trials in biotech, pharmaceutical, and/or CRO environment.
- Oncology experience required (hematology, and specifically lymphoma or multiple myeloma experience highly preferred).
- Sponsor experience required.
- Immunotherapy or cellular therapy experience highly preferred.
- Excellent knowledge of clinical operations and experience with clinical study conduct from start-up through close-out.
- Expert knowledge of ICH GCP and FDA regulations.
- Ability to work, lead and motivate a cross-functional matrix team.
- Excellent negotiation and conflict management skills; ability to influence change and process improvements internally and at clinical sites and CROs.
- Strong team orientation, with excellent written and oral communication skills.

Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- Full-time onsite work at Company's headquarters in San Diego, CA or in South San Francisco, CA
- Up to 25% time traveling to clinical sites 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.

For consideration send cover letter and curriculum vitae to: careers@fatetherapeutics.com and reference job 422SW.

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.