Director / Associate Director, Clinical Outsourcing
Job Code 430SN

Description

Fate Therapeutics is seeking an experienced Associate Director/Director, Clinical Outsourcing to lead key vendor sourcing activities from Requests for Information/Proposals (RFI/RFP) to vendor selection and will ensure the successful development and negotiation of clinical trial agreements with investigative sites. This is a full-time position located remotely in the San Francisco Bay Area or at our corporate headquarters in San Diego, CA reporting to the Senior Director, Clinical Development Operations.

Responsibilities

- Responsible for Clinical Development vendor sourcing and evaluation activities including drafting, submitting and managing RFI/RFP, proposal comparison and analysis, coordination of bid defenses and proposal review meetings, and communication of vendor award and non-award notifications.
- Partner with Clinical Compliance, QA, and Clinical Development to ensure vendor selection processes are efficient and compliant with ICH GCP E6, and oversee vendor risk mitigation per ICH GCP E6 guidelines.
- Responsible for partnering with Finance, Legal and Procurement to manage clinical vendor contract lifecycle, including Statement of Work (SOW), Change Orders, Rate Cards, and Functional Service Provider (FSP) models.
- Partner with Legal and Purchasing colleagues to establish Confidentiality Agreements, Master Service Agreements.
- Responsible for development and management of vendor key performance indicators (KPIs).
- Partners with vendors and internal stakeholders to identify, manage, escalate and resolve issues related to vendor performance.
- Facilitates and executes supplier governance meetings and operating reviews.
- Continually identifies opportunities to reduce costs, increase efficiency, optimize service provider relationships and value, and mitigate risk.
- Identifies, develops and implements Clinical Development outsourcing strategies, processes and procedures.
- Partner with Clinical Operations, Legal, and Finance to ensure successful negotiation and on-going management of clinical trial agreements and budgets with investigative sites.
- Partners with functions within Clinical Development and Finance to support budget/forecasting and variance management activities.

Knowledge/Skills/Abilities

- Expertise in outsourcing and contracting best practices for all phases of clinical research
- Understanding of the drug development process and cross-functional responsibilities including: clinical trial design, budget negotiations, study start-up and execution, CRA and site management, safety reporting, data management, and biometrics.
- In-depth experience soliciting and critically evaluating service provider proposals, negotiating SOW terms, and growing and fostering long-term, healthy strategic relationships.
- Strong knowledge of Generally Accepted Accounting Principles (GAAP).
- Proven track record of supporting financial processes, including budgeting/forecasting and variance management.

- Strong analytical and modeling skills; able to make data-driven recommendations.
- Strong interpersonal, communication and presentation skills to be able to engage with all levels both internally and externally.
- Self-motivated and adaptable to a dynamic environment with the ability to support successful change.
- Comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based upon changing priorities.
- Applies good judgement and professional expertise in new situations.
- Able to develop and mentor staff.

Qualifications

- BS/BA degree in related discipline and at least 7 years of related experience for an Associate Director (at least 10 years of related experience for Director).
- At least 5 years of experience in a clinical outsourcing, site budgets, or finance function.
- Advanced degree preferred.
- Experience within pharmaceutical/biotech industry preferred.
- Excellent people management skills with the ability to influence across the organization.
- Lead and thrive in an interactive, team-oriented culture.

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 430SN.

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.