Associate Director / Senior Manager, Clinical Site Budgets & Clinical Outsourcing
Job Code 431SN

Description

Fate Therapeutics is seeking an Associate Director / Senior Manager, Clinical Site Budgets & Clinical Outsourcing responsible for the development of study-specific site budget templates and for the direct negotiation of site budgets with investigative sites. The successful candidate will lead key vendor sourcing activities from Requests for Information/Proposals (RFI/RFP) to vendor selection 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 Director, Clinical Outsourcing.

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.
- Responsible for developing and negotiating clinical trial budgets with investigative sites, ensuring fair market value (FMV) compliance of clinical trial budgets, and managing the site clinical trial agreement (CTA) development timeline.
- Partners with Clinical Operations, Clinical Science, Finance and externally as needed to develop study specific site budget template and negotiation parameters.
- Partners with Clinical Operations and Legal to develop site contracting timelines, tracks progress and provides regular updates to internal partners and study teams. Supports delivery of fully executed CTAs.
- Identifies risk and escalates appropriately risk is identified during budget negotiation process.
- 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.
- Participates in and may lead supplier governance meetings and operating reviews.
- Uses internal and external data to perform site budget analysis and provide recommendations.
- Supports budget/forecasting and variance management activities as needed.
- Participate in the development and ongoing improvement of departmental processes and procedures.

Knowledge/Skills/Abilities

- This role requires an in-depth knowledge of negotiations of clinical trial budgets, and an understanding of the drug development process and cross-functional responsibilities.
- Knowledgeable in the use of industry benchmarking data sets (e.g. Grantplan, Medicare, etc).

- Experience 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, 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.
- Highly skilled in conflict resolution with the ability to resolve problems independently.
- Ability to multi-task within and across projects, prioritize and manage timelines effectively.
- 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.

Qualifications

- BS/BA degree in related discipline and at least 5 years of related experience for Senior Manager (at least 7 years of related experience for an Associate Director).
- At least 5 years direct site budget negotiation experience.
- Experience within pharmaceutical/biotech industry required.
- Experience with oncology or cell-therapy preferred.
- Experience with US and global site budgets preferred.
- Experience with complex trial designs preferred.
- 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 431SN.

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.