Job Description

Director of Clinical Operations

Why Nuvig

Be a part of a potential game-changer for patients with autoimmune disease! Nuvig Therapeutics is developing drugs that use one of the body's natural mechanisms for re-balancing the inflammatory response in chronic autoimmune disease. This mechanism should be active in a range of autoimmune diseases, without the inherent side effects and safety concerns that accompany long-term treatment with existing therapies that can make patients immunocompromised, or at risk for cancer. As one of the initial employees in a pre-clinical stage, growing company, this is an opportunity to earn an early equity position and play a key role in the success of the organization. Join us in making a dramatic difference in patients' lives!

Position Summary

The Director of Clinical Operations will be responsible for implementing multiple clinical trials. This person is responsible for the execution of the clinical trial operational plans to meet the overall development strategy and ensure that clinical trials are conducted in a timely fashion and meet company goals and budgets. This role will lead the CRO/vendor selection process, contract negotiation, and execution. The Director of Clinical Operations will oversee work performed by Contract Research Organizations (CROs) and other vendors. This role will report to the VP of Clinical Operations.

Responsibilities

Clinical trial execution and oversight:

- Responsible for tactical implementation of clinical development plans by managing timelines, budgets, and resource requirements
- Responsible for the development and content of risk mitigation plans to ensure clinical trials are on time and within budget
- Ensure successful implementation of clinical trial operational plans ensuring that clinical trials are conducted in a timely fashion and compliant with SOPs, GCP, and regulatory guidelines, company goals, and budgets, working collaboratively with the clinical operations group and cross-functional team
- Responsible for the preparation of Clinical Protocols, Investigator's Brochures (IBs), Case Report Forms (CRFs), Informed Consent Forms (ICFs), and Clinical Study Reports (CSRs)
- Leads CROs/vendors selection process for outsourced activities, including the development of scope of services agreements, budgets, plans, and timelines
- Manages CRO/vendor agreements, ensuring that change orders and budgets meet clinical operations specifications
- Review invoices for accuracy compared to operational plans, budgets, and work known to be performed by CROs/vendors
- Liaise with CROs/vendors to ensure study execution and deliverables are being met
- Participates in patient recruitment activities and the development of patient recruitment plans and backup plans, e.g., by liaising with patient advocacy organizations
- Identifies, recruits, and develops relationships with clinical investigators and site staff in collaboration with Medical Monitor and Clinical Operations leadership
- Oversight of contract and budget negotiations with clinical sites

- Ensures that all supportive study-related documents are completed (e.g., Monitoring Plan, Study Reference Manual, Laboratory Manual, Pharmacy Manual, Source/CRFs, including electronic documents
- Ensures that all monitoring activities and processes are complete, including training of internal and external resources, and are compliant with SOPs, GCP, and regulatory guidelines, company goals, and budgets
- Development/coordination of study training for the study team, investigational sites, and vendors
- Oversight of required country regulatory (e.g., CTA, MoH) and country/site IRB/IEC/approvals

Build operational infrastructure:

- Partner with the VP of Clinical Operations to develop staff, structure the department, and create a highly desired work environment for attracting and retaining highly qualified clinical operations professionals
- Build, manage, and nurture clinical operations staff and direct reports
- Develop and ensure compliance with company SOPs and guidelines, FDA regulations, and current ICH GCP guidelines
- Evaluate and analyze tools and processes to support outsourcing efforts
- Work with the clinical operations team to identify and develop innovative systems that enhance clinical trials, clinical program management, and/or department efficiency. Interface effectively with other groups within the organization
- Work with senior management to develop and achieve corporate goals and work with clinical operations staff to achieve the established corporate goals within the expected time frames
- Act as a key resource to provide financial information related to clinical development and interface with the finance group to manage trials costs

Experience, Skills, and Education

- BA/BS degree or higher, preferably in life sciences
- Minimum of 8+ years of clinical operations experience with a thorough understating of cross-functional processes, including clinical supply and data management
- At least 4 years of clinical operations line management experience
- Strong knowledge of Good Clinical Practices and ICH guidelines and their application to the conduct of clinical trials
- High proficiency in clinical studies involving complex design issues (e.g., multiple arms, crossover, double-blind, and multi-center) in all phases of pre-approval clinical trials
- Strong analytical and problem-solving skills
- Proven ability to provide scientific and clinical expertise to a clinical development program
- Maintain a high level of professional expertise through familiarity with industry trends, new regulations, and clinical literature
- Must be a demonstrated self-starter and team player with strong interpersonal skills
- Must have the ability to build and maintain positive relationships with management, peers, and subordinates
- Excellent written and verbal skills required
- Must display strong analytical and critical thinking skills
- Attention to detail required

This job description is for the Director level. We encourage candidates of all levels to apply as there is often flexibility in job titles and responsibilities.

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What We Offer

- A culture inspired by our values: (e.g., patients first, teamwork, scientific rigor and curiosity)
- A collaborative, data-driven pre-IPO start-up environment where we inspire each other to always perform at our best and focus on advancing science that will help patients
- Learning and development resources to help you grow professionally and potential for advancement for stronger performers
- Competitive compensation (Base & Performance Bonus) and stock option package (equity in an early-stage company)
- Rich medical, dental, and vision insurance plans
- Paid Term Life and AD&D, STD, and LTD plans
- Employee Assistance Program (EAP) and Travel Assistance Program
- Generous company holidays, sick time, and flexible PTO
- Flexible work schedule (on-site/remote or hybrid)
- Kitchen stocked with a variety of healthy and delicious snacks and drinks
- Free electric car charging on site

About Nuvig

Nuvig Therapeutics, Inc., headquartered in Redwood City, CA is a science-driven research and clinical development organization focused on fundamentally transforming how we approach and treat inflammatory and autoimmune diseases. Our first product candidate is a recombinant protein that selectively activates a class of immune regulatory receptors that are involved in rebalancing immune function following inflammation. Additional efforts are focused on engineering full-length therapeutic antibodies to maximize their ability to control aggressive autoimmune diseases. The company was founded in 2021 by veterans in this industry and closed a $47 million Series A financing, led by Novo Holdings A/S and Platanus, joined by Bristol Myers Squibb, Digitalis Ventures, and Mission BioCapital.

At Nuvig, we believe that a diverse, open, and inclusive environment and culture is key to our success. We will not be influenced in recruiting, hiring, promoting or any other employment practices by race, color, citizenship status, national origin, ancestry, sex, sexual orientation, gender identity/expression, age, religion, physical or mental disability, medical or genetic condition, marital status, veteran status, or any other characteristics protected under applicable federal, state and local laws. Nuvig will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable laws.