Job Description

VP 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 VP of Clinical Operations will provide leadership and direction ensuring optimal productivity and optimization of operational resources for new and ongoing clinical trials of Nuvig products. The candidate will be highly motivated, proactive, have excellent verbal and written communication skills, extensive experience and value a collaborative environment and a team approach. The VP of Clinical Operations will identify and manage outside partners to optimize current and future trials and establish appropriate clinical operations infrastructure including SOPs to support global submissions. The candidate will be a key member of a cohesive, high performance team. This position will oversee operational activities with an emphasis on excellent clinical trial execution within timelines and budget resulting in high quality data. This role will report to the Chief Medical Officer.

Responsibilities

- Direct the successful execution of clinical trials programs within the established timelines and clinical milestones by taking a hands-on approach, with direct responsibility for end-to-end execution of clinical protocols.
- Lead Clinical Operations Teams to expedite execution of clinical trials, including participating in the design, implementation and review of clinical protocols and study reports for scientific and operational accuracy
- Acquire and sustain advanced knowledge of the therapeutic area and product and clinical trial setting. Ability to understand, interpret and communicate clinical information including literature reviews, competitive intelligence, and changing treatment paradigms to apply knowledge to support a robust clinical development strategy
- Establish and build a highly productive, motivated Clinical Operations function and promote highly effective teams. Hire, manage, and ensure appropriate training for staff.
- Establish strong interaction with the cross-functional partners within the company to enhance the efficiency of clinical trial conduct. Serve as the escalation point of contact for internal/external team members
- Responsible for timely delivery of high-quality clinical study data; collaborate to present clinical study results to the cross functional team and to the company
- Identify, qualify, develop, and manage relations with clinical trial sites, including collaborating with Principal Investigators, CRO, other vendors, and external stakeholders/partners on developing robust study protocols. Drive site selection and patient recruitment programs that deliver

enrollment targets. Work closely with study investigators and site staff to ensure timely and high-quality execution of clinical studies

- Lead or assist in writing, reviewing, and/or approving clinical project deliverables such as scope definition documents, investigational product labeling/kitting, Pharmacy Manuals, informed consent, IRB/EC and HA submissions/approvals, site activations, monitoring plans and tools, CRF's, DMP edit checks, safety plan, Safety Management Team and DMC charter, close-out plans, inspection readiness plans, and CSRs
- Responsible for the selection process of CROs and vendors. Problem solve and participate in CRO governance.
- Responsible for assisting with strategic planning for site/country selection, contract negotiations and oversight of vendors, patient recruitment, and ensuring proper study conduct
- Assist with the development of study presentations, handouts, and oversee coordination of Investigator Meetings, Advisory Boards, Study Monitoring boards, Steering Committees. Assist with publications and scientific presentations
- Ensure that all studies are conducted with the highest level of ethical and safety standards and follow GCP and all regulatory policies. Provide operational expertise to internal and external teams (CMC, regulatory affairs, non-clinical, medical writing, biometrics, and pharmacovigilance; CROs, consultants) to ensure that Clinical Development scientific and medical strategies are met
- Develop and effectively manage annual budget for clinical activities, resource projections, and budget forecasting
- Provide senior management with timely updates on clinical trial progress, and mitigate effects of changes in scope, schedule and resources on timelines and key deliverables.
- Responsible for development of appropriate Clinical Operations infrastructure including SOPs, work instructions and study tools. Contribute to SOP development in other functions.
- Review contracts and work closely with legal to ensure execution of contracts per company requirements and to planned timelines

Experience, Skills and Education

- Minimum 12 years of experience in the Clinical Operations with a proven track record of people and project management
- BS/RN, PA, NP, PharmD degree or equivalent in a scientific or health care field desirable. Advanced degree a plus.
- In-depth clinical trial management experience. Hands-on experience with all clinical trial components (e.g., monitoring, data management, contracts, report writing, etc.)
- A clear understanding of the components of the pharmaceutical development pathways from lead optimization to NDA filing and the necessary interdependency of these components.
- Comprehensive understanding of pharmaceutical regulatory requirements and impact on clinical trial operations
- Experience managing complex situations with CROs and other vendors. Be comfortable working at both a detailed level and a big picture level when necessary.
- Excellent strategic skills with the ability to influence decisions at a senior level, both internally and externally, and to communicate complex clinical issues in a scientifically sound and understandable way.
- Experience with building clinical operations infrastructure from the ground up including writing of SOPs, developing and implementing development tools
- Demonstrated leadership ability with experience leading cross-functional teams
- Detail focus with ability to manage technical/scientific aspects as well as operational components and milestones, and to translate to internal and external staff

- Excellent interpersonal skills with exceptional project and people management skills
- Energetic, self-starter, able to multi-task and thrive under pressure and tight timelines
- Must be flexible, detail-oriented with the ability to work as a team player and the ability to work in a fast-paced environment
- Clinical operational experience in a start-up environment and experience in rare/orphan disease indications are highly desirable
- Moderate travel required

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.