Job Description

Clinical Trials Manager

Why Nuvig

Be a part of a potential game-changer for patients with autoimmune disease! Nuvig Therapeutics is developing therapies that induce endogenous self-tolerizing mechanisms as treatments for autoimmune disease. This mechanism should be active in a broad spectrum of autoimmune diseases, without the inherent side effects and safety concerns that accompany long-term treatment with existing therapies that leave patients immunocompromised, or at risk for cancer. Our Development Candidate NVG-2089 advanced to a Ph 1b in patients early 2024. This is an opportunity to play a key role in the success of an early-stage organization with an early equity position. Join us in making a dramatic difference in patients' lives!

Position Summary

The Clinical Trial Manager manages overall operation of one or more clinical studies including project planning, budget, resource management, and management of contract research organizations (CROs) and other key functional service providers (central labs, data management, central photography etc.). Ensures compliance with company SOPs, GCP, and regulatory guidelines. Recommends and implements innovative ideas to impact clinical trials management. Coordinates with departmental and corporate management to ensure appropriate fiscal oversight, including management of vendor scopes-of-work and change orders. Oversees clinical trials team at service providers and manages all aspects of day-to-day study operations. Acts as a cross-functional liaison to ensure study is executed according to timeline, milestones and within budget.. Ensures a positive, collaborative team environment and escalates issues to the supervisor(s) as appropriate. The Clinical Trial Manager will report to the VP, Development Operations.

Responsibilities

- Leads all efforts in support of 1-4 clinical trials (depending on size and complexity) from protocol design to final deliverables, in accordance with specified timelines, budgets, and associated corporate goals.
- Ensure adherence to study protocols, SOPs
- Participates in the assessment and selection of CROs, sites, and other vendors; may perform site or vendor visits, request, and review proposals, and provide input into scope of work.
- Acts as primary point of contact for CROs and other vendors as needed. Represents the company on vendor calls, with or without management oversight, and ensures CRO personnel adhere to project milestones with particular attention to timelines, costs, and quality of deliverables.
- Coordinates critical decisions among key stakeholders including Nuvig personnel, scientific advisers, and vendor representatives. Escalates issues appropriately.
- Provides strategic and tactical input on clinical trials execution and supports in providing updates to project teams, managing timelines cross-functional workstreams, ensuring alignment on key deliverables, anticipating and mitigating risks, scenario planning, and driving accountability across the organization.
- Supports in the development and update of program timelines and integrated development plans.
- Ensures that participating investigators adhere to GCP and applicable regulations by reviewing monitoring visit reports and direct communication with CRO personnel and Nuvig CQA or designee.
- Identifies and escalates any significant compliance issues to management.
- Takes personal responsibility for ensuring regulatory compliance and delivery of high-quality data via all appropriate means.
- Oversight and input of regulatory and IRB/Ethics Committee submissions and responses to questions as required.

- Reviews and contributes to protocols, IBs, ICFs, CSRs, INDs, BLAs, and other clinical and regulatory documents.
- Represents the company as needed at professional meetings and presents clinical operations materials and provides training at such events as needed.
- Provides ongoing assessment and feedback on departmental policies and procedures toward increased efficiency and quality of deliverables. Contributes to the development of SOPs and other procedural documents.
- Develops metrics and reports as needed in conjunction with vendors, other clinical operations personnel, and Nuvig functional leads. Summarizes and presents these data as required.
- Collaborates with Finance and Legal to oversee program/vendor budgets, including quarterly/yearly budget planning reconciliation (short- & long-term planning), invoices, and contracts.
- Participates as a core member of the Development Operations leadership team involved in developing departmental/functional organizational structure, goals, and resourcing.
- Leads and facilitates sub teams meetings (Study Execution Team (SET), Clinical Development Team (CDT) and vendor meetings).
- Responsible for tactical implementation of clinical development plans by managing budgets, and resource requirements.

Knowledge and Skill Requirements:

- Bachelor's degree, preferably in a scientific or health-related discipline.
- Minimum of 6 years of clinical and related experience with at least 2 years of clinical trial management experience in an industry setting such as a CRO or pharmaceutical company. Trial management experience gained at academic or other not-for-profit institutions involved in industry-sponsored research may supplement this requirement at the discretion of the hiring manager.
- Excellent understanding of GCP, ICH, FDA, EMA, GDPR etc. regulations.
- Clinical experience/background (e.g., RN, PA, or medical office) also a plus.
- Demonstrated ability to develop positive working relationships with individuals and teams both inside and outside the company.
- Must have proficiency with MS Office as well as demonstrated ability to learn other project management and clinical trial software as required.
- Demonstrated ability to work independently, escalate issues appropriately, and to ensure a solutions-oriented approach to the identification and mitigation of risks to project milestones, budgets, and quality.
- Willingness to travel up to 20% of the time.

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
- Health, Limited, and Dependent Care FSA; HSA with company contributions
- 401(k) with company matching
- Pre-Tax Commuter Benefits
- Paid Term Life and AD&D, STD, and LTD plans
- Employee Assistance Program (EAP)
- Generous company paid holidays and flexible PTO
- Flexible work schedule (on-site/hybrid)
- Kitchen stocked with a variety of healthy and delicious snacks and drinks
- Free electric car charging on site

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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 NVG-2089 is a recombinant, human IgG1 Fc fragment that has been engineered to target inhibitory Fc receptors and modulate immune response. 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 industry veterans 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.