Job Description

Clinical Research Associate/
Sr. Clinical Research Associate

Why Nuvig
Be a part of a potential game-changer for patients with autoimmune disease! Nuvig Therapeutics is developing novel immune therapies to treat a broad spectrum of autoimmune diseases. Our treatments are developed to be active for a broad spectrum of autoimmune diseases, without the inherent side effects and safety concerns of long-term treatment with existing therapies, such as immunodeficiency and increased cancer risk. In early 2024, our Development Candidate NVG-2089 advanced to a Ph 1b trial in patients. This is an opportunity to play a key role in the success of an early-stage organization working to advance innovative and transformational therapies to improve treatment options for patients. Join us in making a dramatic difference in patients' lives!

Position Summary
The in-house (Sr.) Clinical Research Associate (CRA) is responsible for the coordination and oversight of activities involving the planning, initiation, and management of clinical trials. This role focuses on enrollment, data quality, and maintaining strong relationships with investigational sites while ensuring adherence to protocols, SOPs, and regulatory guidelines such as ICH/GCP. The (Sr.) CRA coordinates the activities performed by CROs and other vendors and supports internal team members in the oversight and execution of the study, including timely escalation of issues that arise as appropriate. Acting as a cross-functional liaison, the CRA ensures that the study is executed according to the established timelines and milestones while remaining within budget. This role is vital in fostering a positive and collaborative team environment. The (Sr.) CRA will report to the VP, Development Operations.

Responsibilities
- Support study team in adherence to timeline, study quality, budget for assigned studies and sites
- Support communication between the sponsor, CRO, site personnel and other study vendors
- Support execution of internal team meetings, development of meeting minutes, and timely distribution to cross-functional team members
- Support the maintenance of internal study logs and trackers (risk log, enrollment trackers, site activation, training logs, etc.)
- Lead the periodic reviews and maintenance of study level TMF and oversight of CRO management of TMF
- Assist with the management and oversight of clinical trial systems (UAT, system access management, system vendor oversight)
- Lead development and distribution of study newsletters
- Support internal site payment process (accessing reports from EDC, verification of site activity and confirmation of site payment)
- Support study level IP management activities including IP accountability and reconciliation process for assigned studies
- Support study level lab sample management activities
- Develop and manage study level storyboards
- Support Investigator Meeting planning activities and planning of other external meetings
- Participate in collaborative efforts (e.g., CRA, protocol development, and management, etc.)
- Participate in CRO and other vendor selection process and ongoing meetings

- Prepare study-related documents including Informed Consent Documents (ICD), patient instruction guides, review Case Report Forms (CRF) and study oversight plan
- Track and presents study metrics including site activation, subject screening, and enrollment, CRF completion
- Assist in the development of site budgets and facilitate routine site budget negotiations
- Track that essential documents are received and maintained across assigned studies

Knowledge and Skill Requirements

- Bachelor's degree, preferably in a scientific or health-related discipline
- Minimum of 3 to 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
- Exceptional understanding of GCP, ICH, FDA, EMA, and GDPR 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 ensure a solutions-oriented approach to the identification and mitigation of risks to project milestones, budgets, and quality

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

The salary range for this position is $125,000 – 140,000. Nuvig considers various factors when determining the base compensation, including market survey data, experience, qualifications, and geographic location, which means that the actual compensation will vary.

About Nuvig

Nuvig Therapeutics, Inc., headquartered in Redwood City, California, 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 immunomodulatory Type 2 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. Founded in 2021 by industry experts, Nuvig Therapeutics is well-supported by top tier investors, ensuring robust funding to drive our innovative research and clinical programs forward. Key investors include Novo Holdings, Platanus, Bristol Myers Squibb, Digitalis Ventures, and Mission BioCapital.

If your life and career ambitions are to advance transformative medicines that redefine treatment paradigms, please take a look at our job openings. If you think you would be a good fit for our team, please send your resume and a cover letter explaining how you can contribute to Nuvig to careers@nuvigtherapeutics.com.