Job Description

Clinical Trial Manager, Clinical Operations

Vaxcyte, Inc.

March 2021

Company Profile:

Vaxcyte, Inc. (Nasdaq: PCVX) is a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent some of the most common and deadly infectious diseases worldwide. Our exclusively licensed cell-free protein synthesis platform and our proprietary know how enable us to design and produce optimized protein carriers and antigens, the critical building blocks of vaccines, in ways that we believe conventional vaccine technologies cannot. Our pipeline includes pneumococcal conjugate vaccine, or PCV, candidates that we believe are the most broad-spectrum PCV candidates currently in development, targeting the $7 billion global pneumococcal vaccine market. Our lead vaccine candidate, VAX-24, is a preclinical, 24-valent broad-spectrum pneumococcal conjugate PCV with preclinical proof-of-concept demonstrating potential to replace the standard of care that we expect to advance into clinical trials in the second half of 2021. Our pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of at least 30 strains, including newly emerging strains responsible for invasive pneumococcal disease and antibiotic resistance; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; and VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease by targeting the keystone pathogen responsible for this chronic, oral inflammatory disease. We completed our initial public offering in June 2020, raising $287.5 million in gross proceeds.

Summary:

The Clinical Trial Manager (CTM) will be responsible for creation of clinical trial documents and implementation of the clinical trial activities for one or more studies across our development programs. The CTM may also lead a study with guidance from the Clinical Operations Lead (Associate Director/Director, Clinical Operations and/or Senior CTMs). Working closely with investigative site personnel, CROs, and other study vendors and under the direction of the Associate Director/Director, Clinical Operations and/or Senior CTMs. The CTM will assist in the conduct of clinical trial activities in accordance with Standard Operating Procedures and all applicable regulations governing the conduct of clinical trials.

Essential Functions:

- Manage defined aspects of clinical trials to ensure trials are completed on time and in compliance with SOPs, FDA regulations and ICH/GCP guidelines
- Perform the activities associated with the implementation and monitoring of clinical trials such development of clinical protocols, informed consent forms, investigational plans, study materials (eg, training materials, case report forms, study files, supplies requirements)
- Work with Sr. CTM, Clinical Program Manager, Associate Director/Director, Clinical Operations and Medical Monitor to assist with selection of investigative sites, train investigators and investigative site staff, and prepare materials for investigator meetings
- Assist with maintenance of study timelines including identifying and communicating trial issues that will impact budget, resources and/or timelines
- May lead one lower complexity Study Management Team driving cross functional activities supporting study execution

- Assist with review and critique electronic CRFs for accuracy and completeness; assist with data discrepancy reviews and training as needed
- Assist with development and maintenance of study trackers
- Conduct oversight monitoring activities as needed
- Assist with external vendor partner management. Includes review of invoices for accuracy compared to vendor contract; may aid in the development of technical specifications for vendors (e.g. scope of work)

Requirements:

- BS/BA in Life Sciences or related discipline
- 4+ years industry drug, biologic, vaccine development experience; 1+ years' experience as a Clinical Trial Manager, preferably in a small biotech environment
- Thorough knowledge and understanding of FDA and ICH Guidelines, Good Clinical Practices (GCP), medical terminology, and clinical trials
- Demonstrated experience in building relationships with medical personnel at clinical site(s) to achieve enrollment and other trial goals
- Proficiency with electronic databases (EDC, Central Lab, CTMS) and filing (archiving) systems
- Demonstrated problem solving abilities and strong organizational skills
- Must be self-motivating, able to prioritize and manage a large volume of work, and show attention to detail
- Strong interpersonal skills with reputation for collaboration with colleagues; be a good teammate and have empathy
- Proven experience working with key external stakeholders, Study Coordinators and Investigators, and vendor management
- Outstanding written communication skills including writing technical documents, such as protocols, protocol amendments, informed consent, investigational brochure, pharmacy manual and other trial-related documents
- Ability to travel up to 20% domestic and international
- Strong computer skills with Microsoft Office 365 (outlook mail, word processing, excel spreadsheet, project gantt, powerpoint), document control management systems
- Passion to learn, high integrity, and strong work ethic
- Ability to interface with cross-functional teams and embrace a variety of responsibilities is necessary

Reports to: Senior Director Clinical Operations

Location: Foster City, CA

Compensation: The compensation package will be competitive and includes comprehensive benefits and an equity component.

Send resumes to: careers@vaxcyte.com