Senior Clinical Project Manager/Associate Director, Clinical Project Management

Location: Lexington, MA

About Us: At Nightstar, our mission is to maintain and restore sight in patients with inherited retinal diseases. We are a clinical-stage company focused on developing and commercializing a pipeline of novel and potentially curative, one-time retinal gene therapies for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness, and, for which, there are no currently approved treatments.

Job Purpose: We are seeking a Senior Clinical Project Manager/Associate Director of Clinical Project Management for the Company's Lexington, MA office. This is an excellent opportunity for someone with strong organizational skills and the ability to work independently on a variety of tasks and projects simultaneously. In addition, the successful candidate must have good judgment, be flexible when different tasks arise, and be detailed oriented.

Job Responsibilities:

- Representing the study team to design, develop, execute and deliver the clinical study in accordance with the clinical development plan/strategy and timelines
- Responsible for clinical oversight and execution of a company sponsored clinical development program (including Phases I – III)
- Working on all Phases across functions to ensure a robust and effective approach to marketing submission success
- Lead in the selection and oversight of CRO activities and other clinical vendors to ensure study quality meets Nightstar and regulatory requirements
- Working with medical writers and support staff to author and oversee development of protocols, study reports, Investigator Brochures, and other key clinical documents
- Responsible for identification and selection of investigator sites
- Managing escalation of study related issues and communicates as appropriate with management and other R&D functions
- Ability to anticipate potential study issues and to prepare contingency plans with minimal oversight
- Collaborating with the cross functional teams on clinical activities (drug supply, resolution of data queries, etc.) and on selection and management of clinical vendors
- Maintaining knowledge of therapeutic area, current medical practice and pharmaceutical regulations in order to ensure best practice across all activities
- Reporting directly into the Director of Clinical Operations, with the potential of gaining line management responsibilities

Critical Competencies:

- A minimum of 9 years of industry experience in the biotechnology/biopharmaceutical industry
- Experience in clinical operations and development, from Phase I to III

- Working with medical writers to initiate and write protocols, study reports, IBs, and other key clinical documents (including authorship of sections and critical components when required)
- Working with CROs and overseeing multiple vendors
- Working with multi-national studies
- Leadership experience

Behavioral and Interpersonal:

- Exceptional attention to detail and excellent organizational skills with a desire to roll up one's sleeves
- Excellent oral and written communication skills
- Ability to thrive in a dynamic and fast-paced environment
- Ability to prioritize duties and manage multiple matters from start to finish with minimal supervision with a demonstrated ability to lead change and make independent decisions
- Ability to effectively and positively work with executive-level management
- Ability to handle highly confidential and sensitive materials and information with complete discretion and having good judgment in working with clients, and occasionally under ambiguous or challenging circumstances
- A dynamic self-starter with a positive attitude and strong influencing skills

Education Requirements:

- Bachelor's degree, nursing background is also acceptable