Clinical Project Manager

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 Clinical Project Manager for the Company's Lexington, MA office. This is an excellent opportunity for someone with strong organizational skills and the ability to work on a variety of tasks and projects simultaneously with minimal supervision. In addition, the successful candidate must have good judgment, be flexible when different tasks arise, and be detailed oriented.

Job Responsibilities:

- Working with the clinical team to support design, development, execution, and delivery of the clinical study in accordance with the clinical development plan/strategy and timelines
- Collaborate closely with the Sr. CPM, working on execution and oversight of sponsored clinical trials
- Leading in the oversight of CRO activities and other clinical vendors to ensure study quality meets Nightstar and regulatory requirements
- Supporting the Sr. CPM and medical writers to initiate protocols, study reports, Investigator Brochures, and other key clinical documents
- Responsible for oversight of 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

Critical Competencies:

- A minimum of 7 years of industry experience in the biotechnology/biopharmaceutical industry
- Experience in clinical operations and development, preferably Phase III
- Working with the Sr. CPM and medical writers to initiate and write protocols, study reports, IBs, and other key clinical documents
- Working with CROs and overseeing vendors, preferably in Phase III studies
- Working with multi-national studies

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