Associate Director, Clinical Project Management

Location: London, UK or Waltham, 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 an Associate Director of Clinical Project Management. This position will be based in either the Company's office in London, UK or Waltham, MA. 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