Director of Clinical Operations

London, UK

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: Reporting to the Chief Medical Officer, the Director of Clinical Operations is an integral part of the Clinical Development team. He/she will be responsible for the oversight, development, coordination and management of key clinical trial activities to ensure successful execution in alignment with corporate goals. The Director of Clinical Operations will provide operational leadership and expertise in the implementation and execution of clinical study programs, ensuring the timely completion of deliverables through the development and management of the project timelines and budgets. The Director of Clinical Operations is accountable for successful operational delivery of all studies within the Clinical Development Plan (CDP) through the program lifecycle.

Job Responsibilities:

- Responsible for project management of in-house or outsourced pre- and post-approval clinical trials, including investigator sponsored studies and related activities to ensure execution of those studies
- Manage CROs, vendors and consultants involved in the clinical trial and program
- Establish study milestones and maintain responsibility of study metrics and timelines
- Ensure trial adherence according to company SOPs, ICH/GCP/Federal and local regulations
- Provide oversight of data management activities (monitoring, analysis, review and reporting of data) in compliance with GCP, SOPs and standards for clinical studies to ensure data integrity
- Develop and/or review and approve clinical operations documents including Study Management Plan, Monitoring Plan, Communication Plan, Safety Oversight Plan, Data Management Plan etc
- Ensure appropriate Investigational Product release as per relevant SOP and completion of essential documentation
- Provides leadership within the department on the operational aspects and adapt to ensure efficiencies in of executing clinical development deliverables
- Participate and respond to Quality Assurance and/or regulatory authority inspection audits
- Leverage resources, expertise and knowledge across projects, including specific operational strategies for executing clinical studies globally
- Serve as the Subject Matter Expert in clinical studies involving complex design issues
- Develop and manage team of direct reports
- Lead the operational selection of various vendors and the review of proposal requests
- Oversees contracting and budget-related activities for vendors and clinical trial sites
- Develop and manage clinical trial budgets; proactively provide senior management with necessary updates on progress and changes in scope, schedule, and resources in a timely manner
- Prepare and deliver effective presentations to the Project Team, Senior Management and external parties

- Ensure strong scientific lead in the reporting and interpretation of results

Critical Competencies:

- 10+ years of clinical research experience, with experience in project management, monitoring and CRO management preferred
- Must have experience managing and providing oversight of clinical studies outsourced to third party vendors and be able to effectively manage interactions between functional groups such as monitoring, data management, biostatistics, medical writing, safety, regulatory affairs and QA. Responsible for building and maintaining relationships with clinical investigators/advisors/thought leaders.
- In depth knowledge of clinical operations and vendor management
- Ability to collaborate effectively with the clinical operations team, cross-functional team members and external partners including CROS, Vendors, Investigators and site staff.
- Function across UK and US company locations
- Excellent knowledge of GCP, ICH and FDA regulations.
- Previous leadership experience
- Strong understanding of QA, Auditing and Compliance
- Experience working across multiple sites (including both US and UK)
- Experience with Phase II/III studies (preferred)
- Experience bringing a product from Phase III to NDA (preferred)
- Experience with rare diseases, specifically ophthalmology (preferred)

Behavioral and Interpersonal:

- Passionate about your work and display a high level of emotional intelligence in your decision making
- Understand, appreciate and thrive in a growing organization and have the desire to learn new skills to contribute to company success
- The ability manage various projects, solve problems and deliver on commitments
- Effectively communicate and interact with Investigators/Sub Investigators and clinical personnel
- Understand strategy, transition to execution and effectively collaborate cross functionally
- Excellent communication and collaborative skills
- Detail oriented and good problem solving ability
- Independently motivated

Education Requirements:

- BA/BS in science or healthcare degree