



Clinical Research Associate

Lexington, MA / 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: We are seeking a Clinical Research Associate for the Company's Lexington, MA and London, UK office. This is an excellent opportunity for someone with strong organizational skills and the ability to work in a team-oriented environment. In addition, the successful candidate must have good judgment and be detailed oriented.

Job Responsibilities:

- Develop strong working relationships and effective communication with collaborating study teams, Nightstar Clinical Development and other Nightstar functional departments
- Perform data verification visits, including generation of visit reports for studies under Investigator held INDs
- Collaborate with field-based monitoring staff to assist in data verification activities
- Track and escalate study issues to the Study Manager
- Help author Data Verification Plans for investigator held IND studies. Assist in development of operational plans
- Provide timely, quality study metrics to study teams using a variety of tracking tools (tables, databases, spreadsheets and files)
- Work with specialty lab vendors and research scientists to manage laboratory sample transfer from collaborative trial sites to specialty labs

Critical Competencies:

- A minimum of 2 years of experience in biotech/pharma industry within clinical operations
- On-site monitoring experience
- Strong working knowledge of FDA & ICH/GCP regulations and guidelines and thorough knowledge of clinical monitoring procedures

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 in life science or related discipline.