Associate Director, Head of Statistical Programming

Location: Lexington, Massachusetts

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 into Vice President, Head of Statistics, the successful candidate will provide leadership and coordination of Nightstar's statistical analysis and programming activities. The candidate will be expected to manage the consultants and vendors on statistical programming and assure adherence to relevant regulatory requirements and company Standard Operating Procedures (SOPs).

Job Responsibilities:

- Produces timely statistical analyses of clinical and preclinical data per protocols and Statistical Analysis Plans; develops statistical programs and produces programmed outputs used to create integrated scientific reports for clinical trial results.
- Provides statistical input for Statistical Action Plans, publication activities, scientific presentations and promotional material.
- Participates in study team meetings as a representative of the Biostatistics function. Communicates statistical issues and acts as a statistical/programming resource to the development teams.
- Participates in the assessment, selection and evaluation of CROs
- Participates in the review of Case Report Forms (CRFs), CRF annotations, Statistical Action Plans, and TLGs shells and TLGs.
- Interacts with CROs involved in data management/analysis activities to ensure that their statistical analyses and resulting outputs are accurate and consistent with the contractually agreed upon deliverables; works with vendor staff to characterize and resolve issues related to data analysis.
- Creates/Reviews derived dataset specifications and the related analysis datasets.
- Develops SOPs and training guidelines related to statistical programming.

Critical Competencies:

- Master's degree in a quantitative sciences discipline (e.g., Statistics, Mathematics, Computer Science) and a minimum of 12 years progressively responsible experience in statistics or statistical programming experience in a pharmaceutical, biotechnology, CRO or related environment.
- Excellent SAS programming skills (e.g., Base SAS, SAS/Stat, SAS/Graph, SAS macros, ODS)

- Clinical Data Interchange Standards Consortium (CDISC) experience
- Working knowledge of the theory and application of relevant statistical methods, such as linear models, non-parametric analysis, categorical data analysis, survival analysis, and longitudinal data analysis
- Proficiency with Microsoft Office.
- Excellent verbal and written communication and skills
- Ability to work independently and collaboratively, as required, in a fast-paced, matrixed, team environment consisting of internal and external team members
- Analytical thinker with excellent problem solving skills and the ability to adapt to changing priorities and deadlines
- Excellent planning, organization and time management skills including the ability to support and prioritize multiple projects