



Director, Biostatistics

Location: 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: Reporting into Vice President, Head of Biostatistics, the successful candidate will direct and manage Biostatistics activities across clinical programs to ensure high quality statistical deliverables. The position will actively support clinical development programs by working closely with colleagues in clinical development, statistical programming, data management, medical writing, clinical operations, and regulatory affairs to advance drug development.

About the role:

- Collaborates with colleagues in Clinical Development to design and execute clinical trials.
- Represent biostatistics in meetings with regulators, KOLs, partners, and other stakeholders.
- Responsible for Biostatistics deliverables across programs/studies.
- Ensure that clinical development programs meet scientific, regulatory, and quality requirements
- Perform trial statistician responsibilities, including attendance of study team meetings, authoring SAPs, design of studies, review of protocols/amendments, conducting exploratory data analyses, and performing just-in-time analyses.
- Manages CRO statistical deliverables.

Critical Competencies:

- Ph.D. in Biostatistics or Statistics or Equivalent with at least 10 years of experience.
- Experience with NDA/BLA submissions and regulatory interactions.
- Proven knowledge and expertise in statistics and its applications to clinical trials.
- Excellent written and oral communication and presentation skills.
- Understanding of ICH guidelines as well as general knowledge of industry practices and standards.
- Working knowledge of CDISC standards.

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