Stealth BioTherapeutics, Inc. is an innovative biopharmaceutical company committed to bringing patients mitochondria targeted therapies to treat both common and rare diseases. Driven by a desire to help patients with unmet medical needs, our team collaborates with well-recognized institutions, physicians, and scientists to develop the next generation of therapies focusing on mitochondria dysfunction in many diseases.

Position Title: Associate Director/Director, Biostatistics

Position Summary:

The Associate Director/Director, Biostatistics is a hands-on position reporting to our Executive Director of Biometrics responsible for overseeing statistical programming, analysis, and reporting across clinical studies. This role blends leadership with active execution – developing statistical output, ensuring data integrity, and partnering closely with cross functional colleagues in a fast-paced environment. The Director will design and implement efficient programming workflows, ensure regulatory compliance, and help shape data strategy from early development through pivotal trials and submissions.

Responsibilities:

- Lead statistical programming to plan, execute, and deliver statistical outputs for clinical trials and regulatory filings.
- Oversee development, validation, and maintenance of SDTM and ADaM datasets, tables, listings, and figures (TFLs).
- Provide statistical inputs to protocols, data monitoring committee (DMC) charters, clinical study reports (CSR) and other study-level documents, in collaboration with the clinical team.
- Provide statistical programming and analytic support for statistical analysis plans (SAPs), randomization, mock shells, and integrated analyses (ISE/ISS).
- Contribute to abstracts and manuscripts for publications.
- Review study Case Report Forms, data management plan and other related documentation to ensure specific study protocol statistical requirements are met.
- Manage statistical, programming and data management vendor deliverables.
- Ensure quality, reproducibility, and compliance with CDISC and 21 CFR Part 11 standards.
- Review relevant sections of the electronic common technical document (eCTD).

Competencies:

- Strong analytical skills; expert knowledge of programming, with a wide range of analytic methods, statistical software.
- Strong organizational and multitasking abilities, problem solving skills, and attention to detail.
- Excellent oral and written skills; ability to effectively communicate statistical information to non-scientists, and a willingness to educate internal team.

- Sound judgement with the ability to work in a fast-paced environment and flexibly adapt to changing timelines.
- Ability to effectively collaborate with internal stakeholders and manage the statistical work of external stakeholders/vendors.

Requirements:

- PhD or MS in Biostatistics or statistics. 5+ years' drug development experience with biopharmaceutical companies.
- Thorough understanding of statistical principles and clinical trial methodology with demonstrated expertise in statistics, as well as application to clinical trials and regulatory submissions.
- Proficiency with statistical software including SAS, R and Python.
- Programming and data management experience, as well as rare disease and/or ophthalmology clinical trials experience, is preferred.