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: Senior Director, Biostatistics

Position Summary:

In this newly created, hands-on, position reporting to our Vice President of Clinical Development, you will play a key role in transforming clinical data into analyses to further advance progress of Stealth sponsored clinical studies. As an important member of our program teams, you will work collaboratively with cross functional colleagues to design and support data collection, analyses, efficacy interpretation, safety, and biomarker results, in addition to managing the services of our statistical vendors.

Responsibilities:

- Serve as biostatistical lead in designing and supporting data collection, analyses, efficacy interpretation, safety, and biomarker results as an active participant on the clinical development program teams.
- 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.
- Author relevant sections of regulatory submissions, documents, responses, and address comments by IRB/ECs. Accountable for statistical activities in support of all regulatory submissions/interactions.
- Author/review statistical analysis plan (SAP) for clinical trials and integrated summaries of safety/effectiveness (ISS/ISE); author /oversee development of shells for tables, figures, and listings.
- Contribute to planning, review and finalization of abstracts and manuscripts for publications.
- Apply innovative approaches to study design, analysis methodologies, data exploration, and presentation.
- Define/review randomization procedures and produce randomization lists for clinical trials.
- 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.
- Contribute to biometrics vendor selection, infrastructure development, process improvement, training, SOP development, and enhancement of statistical technical expertise.

- Ensure that biostatistical activities comply with CDISC, health authority regulations, ICH/GCP guidelines and company SOPs.
- Serve as a key contributor to protocol development.
- Ensure study designs are scientifically sound, and that efficacy and safety information meets regulatory requirements of countries and regions within which the drugs will be submitted.
- 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 in Biostatistics or statistics. 10+ 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.