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

Job Title: Associate Director/Director, Clinical Sciences

Position Summary:

In this newly created position, the Associate Director/Director, Clinical Sciences will report to our Executive Director, Clinical Sciences with primary responsibility to further advance progress of our expanding ophthalmology program. In addition to planning, implementing, and managing clinical research studies in collaboration with internal and external stakeholders to ensure trial integrity and success, responsibilities will include providing strategic input and development support for clinical development plans, evaluating and interpreting clinical data, leading data analysis initiatives, reviewing and authoring study-related documents, routinely reviewing patient and study-level data, and serving as the expert for the clinical protocols. Further responsibilities will include developing strong partnerships with the associated internal ophthalmology program teams, as well as with external CROs and advisory committees, to translate scientific insights and development strategy into trial execution.

Responsibilities:

- Contributes to the creation of the clinical development plan in partnership with the Executive Director, cross-functional team members, and external experts.
- Authors, manages, and reviews clinical trial and regulatory documents.
- Analyzes and interprets clinical trial data, collaborating with cross functional stakeholders and medical monitors, to support decision-making and program advancement.
- Provides scientific support throughout conduct of a clinical trial; responds to clinical questions from sites, IRBs/IECs, Health Authorities, and CROs.
- Troubleshoots internal and external conflicts to ensure trial integrity and success.
- Develops and presents protocol training for CROs and trial sites.
- Reviews development of case report forms and other relevant trial-related documents to ensure key data elements are being captured.
- Monitors aggregate level data, and subject data where required, to ensure adherence to protocol and consistency of data collection.
- Establishes and maintains relationships with external experts, investigators, and external partners, including educational and scientific support.
- Participates in scientific advisory boards.
- Develops and maintains knowledge of the therapeutic area, current medical practice, and pharmaceutical regulations to help ensure best practices.
- Liaises between biostatistics and data management to support trial analyses, post-hoc analyses, and publications and congress planning initiatives.
- Develops and delivers effective clinical presentations to internal and external audiences.

Competencies:

- Ability to analyze and interpret clinical data.
- Excellent oral and written skills; ability to effectively communicate complex information.
- Ability to proactively predict issues, resolve problems, and make sound decisions.

- Strong organizational abilities and attention to detail.
- Ability to work independently as well as part of a team.
- Ability to effectively collaborate with internal and external stakeholders.
- Strong understanding of clinical trial design, execution, data governance, dataset structures, and biostatistics.

Requirements:

- Advanced degree in Health-Sciences (e.g. PharmD, PhD, DVM, RN.) and a minimum of 5 years related experience.
- Strong understanding of scientific and clinical research processes.
- Periodic travel.
- Ophthalmology experience is preferred.