Stealth BioTherapeutics, Inc 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

Position Title: Associate Director, Clinical Operations

Position Summary:

We are seeking a resourceful, self-starter with excellent interpersonal and organizational skills to join our growing clinical operations team. S/he is responsible for successful management of clinical trials from protocol concept through the clinical study report. This position is an experienced resource for Clinical trial managers, able to provide direct guidance and has strong decision-making capabilities. Experience and knowledge of end-to-end management of clinical trial conduct, knowledge of the pharmaceutical industry and an understanding of clinical drug development, clinical trials operations are essential. Contributes to the development of SOPs, clinical development plans, and other company initiatives as required. Additional responsibilities include co-monitoring, and managing junior staff as needed.

Responsibilities:

- Ensures clinical trials are executed in compliance with ICH/GCP (Good Clinical Practice) guidelines, regulations, and company SOPs
- Assists in the RFP, selection, qualification, and management of vendors to support clinical trial execution
- Assists in new site initiations and trainings
- Assists in the development and management of site budgets, timelines, and metrics; ensures completion of study deliverables; provides status update reports
- Assists in forecasting clinical trial material & ancillary supplies
- Plans and executes study-specific meetings (e.g., investigator meetings, clinical sub team meetings) as needed
- Assist in reviews monitoring reports and assess non-compliance trends
- Review site audit reports to ensure quality and resolution of site-related issues
- Ensures timely review of protocol deviations and assess impact on study data
- Oversee maintenance of TMF and working study files
- Represents Clin Ops on Product Complaint Committee & audit readiness.
- Partners with clinical scientists to design clinical trial protocols consistent with the clinical development plan

- Participates in departmental planning sessions, SOP development, clinical document reviews
- Manages clinical trial site relationships
- Line manage CTMs and CTAs and help organically grow the department
- Initiates and manages cross-functional meetings to ensure alignment with all program stakeholder

Competencies:

- Strong organizational and multitasking abilities, problem solving skills, and attention to detail
- Excellent oral and written skills
- Ability to effectively communicate complex information
- Ability to manage teams for complex protocols
- Sound judgement with the ability to flexibly adapt to changing timelines
- Ability to effectively collaborate with internal and external stakeholders

Requirements:

- Bachelor's degree in life sciences
- 5+ years of direct clinical trial experience in Pharmaceutical, Biotech or CRO required, with a minimum of 3+ years of global trial management lead/oversight experience
- working knowledge of global regulatory requirements to set up a trial
- sound knowledge of the scientific and clinical research processes
- experience managing external vendors and TMFs
- Preferences include experience in rare disease, CNS and/or Ophthalmology, as well as IND and NDA experience
- Must be able to travel occasionally (approximately 20%)