Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Senior Clinical Trials Manager

Position Summary:
We are seeking a resourceful, self-starter with excellent interpersonal and organizational skills to join our clinical team. The Senior Clinical Trials Manager (Sr.CTM) is responsible for successful management of clinical trials from protocol concept through the clinical study report. Primary responsibilities include management of trial execution, oversight of trial sites, management of vendor and clinical sub teams to ensure timelines, study protocol and regulatory requirements are met. Additional responsibilities include co-monitoring, managing CT. Gov postings and mentoring 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 selection, qualification, and management of vendors to support clinical trial execution
- Assists in pre-study site evaluations as well as 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
- Reviews all SAEs, ensuring Medical Director sign-off, that sites are notified and that company procedures are followed
- Reviews monitoring reports, site audit reports to ensure quality and resolution of site-related issues
- Ensures tracking and review of protocol deviations and assesses impact on study data
- Assists in maintaining 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
- Serves as a point of contact for vendors and oversee day to day vendor activities
- Initiates and manages cross-functional meetings to ensure alignment with all program stakeholders

Competencies:
- Strong organizational and multitasking abilities, problem solving skills, and attention to detail
- Excellent oral and written skills; ability to effectively communicate complex information
- 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 or related area
- 5+ years' experience managing clinical trial execution
- Sound knowledge of the scientific and clinical research processes
- Rare disease and or Ophthalmology experience is desired

- Must be able to travel occasionally (approximately 20%)
- Experience managing external vendors and TMFs
- CRO and NDA experience is a plus