Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Clinical Trials Manager (CTM)

Position Summary:
We are seeking a team player with excellent interpersonal and organizational skills to join our growing clinical operations team. He / She will be responsible for managing clinical trial/s from protocol concept through the clinical study report, providing clinical trial coordination support including clinical status tracking, SAE reconciliation, document management and data review activities in accordance with standard operating procedures, clinical operational plans, regulatory requirements and Good Clinical Practice.

Responsibilities:

- Ensures clinical trial/s are executed in compliance with ICH/GCP (Good Clinical Practice) guidelines, regulations, and company SOPs
- Assists in vendor RFPs, bid compilation and contract management and execution
- Assists in the selection, qualification, and management of vendors and sites 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 study budgets, timelines and metrics; ensures completion of study deliverables; provides status update reports
- Plans the requirements for clinical trial material
- Plans and executes study-specific meetings (e.g., investigator meetings) as needed
- Assists with preparing basic summary reports, Serious Adverse Event/Adverse Event reconciliation for PVG
- Reviews all SAEs, ensuring Medical Director sign-off, that sites are notified and that company procedures are followed
- Reviews monitoring reports to ensure quality and resolution of site-related issues
- Ensures tracking and review of protocol deviations and assesses impact on study data
- Partners with clinical scientists to design clinical trial protocols consistent with the clinical development plan
- Participates in departmental planning sessions, and SOP development
- Manages clinical trial vendor and site relationships
- Initiates and manages cross-functional meetings to ensure alignment with all program stakeholders
- Oversee management of CRF data (EDC), trial-related documents in the Trial Master File (TMF)
- May serve as the point of contact for vendors and oversee day to day vendor activities

Competencies/Requirements:

- Bachelor's degree in life sciences or related area
- At least 2 years of relevant work experience in clinical trial management in a pharmaceutical or

CRO environment

- Excellent verbal and written communication
- Working knowledge of ICH/GCP regulations and clinical protocols
- Demonstrated computer aptitude in MS Office Suite and other systems
- Good working knowledge of management and oversight of CROs and TMFs
- Ability to travel up to 20%
- Accommodates a flexible work schedule according to clinical trial(s) priorities
- Strong interpersonal, organizational and multi-tasking skills; attention to detail
- Perform job duties with minimal supervision and guidance