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

Position Title: Clinical Trial Assistant (CTA/Sr.CTA)

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 providing clinical trial coordination support across all indications including clinical status tracking, document management and data review activities in accordance with standard operating procedures, clinical operational plans, regulatory requirements, and Good Clinical and documentation Practice.

Responsibilities:

- Support the Clinical Team in management of clinical trial documents and site start-up activities.
- Complete study tracking and report on study status/metrics.
- Participate in vendor and internal study team meetings, including drafting of agendas, minutes and other meeting materials as needed.
- Manage trial-related documents in the Trial Master File (TMF); review documents for completeness, accuracy and compliance with protocol and applicable regulations and standard operating procedures.
- Provide administrative support to vendor RFPs, bid compilation and contract management and execution.
- Perform quality checks and follow-up on resolution of open issues to ensure cross functional study team members are compliant with use of required systems and documentation as required.
- Assist with review and preparation of external and internal documentation for assigned trials.
- Track delivery and receipt of required supplies and materials to study sites.
- Support investigator meeting preparation and collection/distribution of materials.
- May participate in the training of CRO teams, investigators, and study team members.
- Assist with administrative functions such as preparing basic summary reports, Serious Adverse Event/Adverse Event reconciliation for PVG.
- May serve as the point of contact for vendors and oversee selected vendor activities.

Competencies/Requirements:

- Bachelor's degree in life sciences or equivalent training required.
- At least 2 years of relevant work experience in clinical trial support, data coordination. 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 eTMFs. Experience with Veeva Vault is highly desired.
- Ability to travel up to 10%.
- 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.