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: Expanded Access Programs Coordinator (Contractor)

Position Summary:
The Coordinator, Expanded Access Programs (EAPs) and Registries, is responsible for assisting in the daily operational activities for Stealth EAPs and Registries that provide early access to SBT drugs to patients who do not have access through other means, and Investigator Initiated Studies (IIS) conducted in collaboration sites and advocacy groups. The EAP Assistant also supports EAP Strategic Team meeting initiatives as needed. Reporting to the Associate Director (AD) EAP Programs and Registries, the position plays a key role in the ongoing maintenance of these programs in terms of adherence to strategy, policy and procedure, as well as in support in managing the day-to-day operations, including case intake and evaluation, vendor management, and continuous improvement initiatives.

Responsibilities:
- Maintain EAP Standard Operating Procedure and Work Instruction documents to ensure consistent application of the programs' rules and update these documents with EAP Associate Director (AD) input.
- Assist in early review of EAP request submissions and determine whether the cases fit the outlined policies; respond to physicians as appropriate particularly for expedited or emergency cases.
- Maintain internal EAP request database (Smart Sheets/Excel).
- Facilitate interactions per SOPs with Medical, Clinical, Regulatory, Supply Chain, Quality Assurance, and other functional areas as needed to review cases and arrive at decisions.
- Coordinate final SBT review of EAP requests for transition to program support vendor.
- Assist in communications with the program support vendor(s), filing meeting notes and coordinating resolution of SBT action items.
- Coordinate with SBT Supply Chain to ensure adequate EAP and other drug supply needs are met for EAP and IIS.
- Maintain the EAP team data repository system and SharePoint folders.
- Aid in updating Regulatory, Quality Assurance, and other functional areas on EAP and IIS activities through maintenance of EAP Sub-Team meeting notes.
- Co-review work instructions, Standard Operating procedures (SOPs), and standards, and support delivery and communication on key outputs, operational/performance metrics.

- Assist with evaluation of safety events, both in EAP and future global clinical safety database. Ensure that required safety information is reported and processed according to all applicable SOPs for IIS.
- Assist in preparing for or conducting internal audits or other inspections.
- Ensure the highest standards for Quality and Compliance practices are adhered to.
- Act as backup to AD during EAP Strategic Team meetings.
- Act as backup to AD for emergency and expedited requests processing.

Requirements/Competencies:

- Bachelor's degree in a relevant life sciences discipline required, ASN preferred.
- 3+ years of experience in a pharmaceutical company, biotech or CRO.
- Preferred experience as Study Coordinator/Manager in Investigator Sponsored Studies/EAP/Compassionate Use, Pharmacovigilance (Safety), Regulatory or Medical Affairs, patient Access.
- Working knowledge of multiple phases of clinical research.
- Knowledge of vendor management processes.
- Ability to professionally interact with all functional areas and levels of the organization.
- Ability to maintain confidentiality with sensitive information.
- Meeting facilitation skills (personal organization, advanced preparation, and follow-up)
- Command of Microsoft Office suite, particularly Excel and PowerPoint, basic working knowledge of clinical database systems.
- The duties of this role are generally conducted in a virtual office environment. As is typical of an office-based role, employees must be able, with or without an accommodation to use a computer; engage in communications via phone, video, and electronic messaging; engage in problem solving and non-linear thought, analysis, and dialogue; collaborate with others; maintain general availability during standard business hours.