Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Expanded Access Program Manager

Position Summary:
We are seeking a dynamic self-starter with excellent interpersonal and organizational skills to join our growing clinical team. He / She will be responsible for managing Expanded Access Programs (EAP)/Managed Access Programs (MAP), providing coordination support including status tracking, IP management, safety reporting, document management and data review activities in accordance with, regulatory requirements and Good Clinical Practice.

Responsibilities:

- Lead the selection, qualification, and management of vendors to support EAP execution
- Lead and co-ordinate the development and management of EAP protocol regulatory document collection, timelines and metrics; ensures timely and quality deliverables; provides status update reports
- In partnering with Tech Ops, lead planning, forecasting and management of clinical supply (IP) for EAP
- Monitors vendor shipments and endures inventory at both the depot and site level
- Co-manages standardized return and destruction procedures as needed
- Accountable to plan, lead and execute EAP Core Team
- Assist Medical for qualification of patients for Named Patient Program (NPP)
- Reviews vendor oversight reports to ensure quality and resolution of site-related issues
- Ensures tracking and review of IP deviations and assesses impact on safety data
- Assists with preparing basic summary reports, Serious Adverse Event/Adverse Event reconciliation for PVG to ensure timely reporting
- Ensure EAP safety data is harmonized with the Argus safety database maintained for Stealth sponsored clinical trials
- Initiates and manages cross-functional meetings to ensure alignment with all program stakeholders
- Assist in assessing product complaints and represent clinical on Product Complaint Team
- Assists with retrieving safety summary reports for EAP
- Will serve as the point of contact for vendors and oversee day to day vendor activities
- May assist in managing IIR and or Registry studies as assigned and other Clinical Operations duties

Competencies/Requirements:

- Bachelor's degree in life sciences or related area
- At least 2 years of relevant work experience in managing clinical trials and Expanded Access/Compassionate Use Program in a pharmaceutical or CRO environment

- Strong project management foundation
- Global and local expertise and experience managing dynamics for Phase I through Phase IV trials
- Excellent verbal and written communication
- Working knowledge of ICH/GCP regulations and clinical protocols
- Working knowledge of drug/device combination product is a plus
- Demonstrated computer aptitude in MS Office Suite and other systems
- Good working knowledge of management and oversight of CROs, IWRS and TMFs
- Ability to travel if and as needed (10%)
- Strong interpersonal, organizational and multi-tasking skills; attention to detail
- Perform job duties with minimal supervision and guidance