

Stealth BioTherapeutics, Inc (SBT) 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: Director/Sr. Director, Clinical Operations

Position Summary

We are seeking a resourceful, self-starter with excellent interpersonal and organizational skills to join our growing clinical operations team. The position is responsible for successful management of clinical trials from protocol concept through the clinical study report. It will also serve as an experienced resource for Clinical trial managers in providing guidance with sound decision-making capabilities. The position will further contribute to the development of departmental SOPs, staff development, and other company initiatives as required. Additional responsibilities include co-monitoring and managing & mentoring junior staff as needed. Experience and knowledge of hands-on management of clinical trial conduct, knowledge of the biopharmaceutical industry, drug development process and an understanding of clinical regulatory landscape, clinical trials operations are essential.

Responsibilities

- Responsible for planning, implementation, execution and management of clinical trials
- Ensures assigned clinical trials are executed in compliance with ICH/GCP (Good Clinical Practice) guidelines, country regulations, and company SOPs
- Contributes to RFP, selection, qualification, and lining up clinical vendors, relevant licenses to support clinical trial execution
- Oversees day to day operations, directly manage CROs and or assigned clinical vendors
- Collaborate with cross functional teams, lead new site selection, startup activities through regulatory green light
- Assists in the development of site budgets, timelines, and metrics; ensures completion of study deliverables on time within budget; provides KPI dashboard/ progress reports to management
- Assists with IMP forecasting, label reviews, procurement of relevant clinical trial supplies, & global packaging timeline
- Plans and executes study-specific meetings (e.g., KOMs, Investigator meetings, Clinical sub team meetings) as needed
- Assists in reviews monitoring reports, audit reports, DM reports to ensure quality data is generated; assess non-compliance trends

- Lead Clin Ops for audit readiness activities for GCP site audits, PAI etc
- Oversee maintenance of TMF and working study files
- Represents Clin Ops on Product Complaint Committee & audit readiness.
- Participates in the creation, review & finalization of clinical documents including trial protocol, IB, ICF, regulatory submissions and CSR
- Participates in departmental planning sessions, SOP development, clinical document reviews, performance reviews
- Manages clinical trial site relationships in collaboration with Med Affairs & Clin Sci leads
- Manage assigned direct reports (CTMs/CRAs/CTAs) and help organically grow the department
- 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 communication skills (oral, written, presentation)
- Ability to effectively communicate complex information
- Ability to manage teams for complex protocols
- Sound judgement with the ability to flexibly adapt to changing timelines
- Ability to proactively build relationships and effectively collaborate with internal and external stakeholders, facilitating alignment among them as needed
- Exhibit ability to anticipate potential trial issues/risks and to prepare contingency plans with minimal oversight

Requirements

- Bachelor's degree/Advance degree in life sciences
- 10+ years of direct multi- phase clinical trials, project, line management experience in Pharmaceutical, Biotech and or CRO required, with a minimum of 5+ years of multi-phase global trial management lead/oversight experience
- Working knowledge of global regulatory requirements to set up trials
- Sound knowledge of the scientific and clinical research processes
- Experience managing external vendors deliverables and TMFs
- Preferences include experience in rare disease, Ophthalmology & CNS
- Must be able to travel occasionally (approximately 20%)