POSITION DESCRIPTION

Position:	Clinical Trial Manager	**Department:**	Clinical Operations
Reports to:	Director, Clinical Operations	**Date:**	January 2021
Location:	New Haven, CT or Remote	**Classification:**	Exempt/ admin. & professional

Position Summary:

Primary point of contact for Clinical Operations aspects of designated projects and responsible for developing successful working relationships with clients (sites, vendors, ancillary departments). Works with clinical group to ensure integrity of the clinical data and Investigator compliance with protocols. Ensures that the clinical trials are performed under GCPs.

Key Responsibilities and Essential Functions:

- Overall management of global Phase I-III studies within various indications and/or therapeutic areas
- Provides strategic operational direction to study teams to meet corporate study goals and timelines
- Manage and monitor tasks and timelines of internal and external resources to achieve program objectives
- Participates in the selection of Contract Research Organizations (CROs). May attend CRO or other vendor meetings such as project kick-off and investigator meetings, quarterly face-to-face meetings, and others as necessary to assure alignment and achievement of study goals
- Provides consistent, regular oversight of CRO and vendor performance including monitoring and site management; co-monitoring of assigned CRAs as needed
- Oversight of associated vendor activities, including but not limited to, data management, e-diaries, IWRS, central laboratories. Performs user acceptance testing on systems as required
- Contributing member of various study and program teams; provides direction to junior staff in creating meeting agendas and documenting outcomes and deliverables
- Oversight of vendor budgets and contracts, in conjunction with Project Lead and Finance department
- Ensure studies are conducted under GCP and ICH Guidelines
- Obtain and review all pertinent study documents from the CRO for study initiation and continuation
- Obtain and review site visit reports from monitor(s) to determine potential study conflicts
- Participate in the writing and review of clinical SOPs
- Travel may be required up to 25% in support of clinical study activities
- Reporting and justification of study metrics to senior and executive management

Qualifications:

- Typically requires a minimum of 8-10 years of related experience or a minimum of 12 years combined education/training and experience.
- Experience in Biotech/Pharmaceutical industry preferred.
- Management experience including outsourcing to Contract Research Organizations (CROs).
- Knowledge of FDA regulatory requirements