75 State Street, Suite 1400, Boston MA 02109 USA

Position Title:	Clinical Trial Manager
Department:	Clinical Operations
Hiring Manager:	VP, Head of Clinical Operations

Our vision is a world where science, passion, and compassion create better todays and more tomorrows.

Clinical Trial Manager Position Overview:

The Clinical Trial Manager is responsible for the management of clinical studies across phases including actively participating in a variety of activities to support and facilitate the efficient conduct of patient trials in our clinical research programs. Reporting to the VP, Head of Clinical Operations you will be responsible for supporting the critical day-to-day clinical study activities, including development of study start-up materials, clinical supplies, case report forms, contracts and budgets, investigator meetings, and regulatory document filings.

Responsibilities:

- In partnership with Clinical Trial Associate, study teams, and Clinical Research Organizations (CROs), support clinical study activities as defined by the clinical trial operating model.
- Managing all aspects of study progress from start-up to close-out activities and assuring adherence to intended timelines to achieve study goals while ensuring compliance with international GCP guidelines/regulations and SOPs/SWPs.
- Provide expert operational oversight and guidance to support prioritization of activities, review and monitor the work performed, metric compliance, and development of contingency plans, among others.
- Coordinating interdisciplinary activities involving study start-up: investigator meeting planning, case report form development, study drug supply design and ordering, development of contracts and budgets, database set-up, regulatory document filing.
- Preparing and/or reviewing study-related documents (e.g., Study Operations Plan, Monitoring Plan, Laboratory Manual, CRF Completion Guidelines, and other study-specific documents or manuals). Preparing/reviewing site study documents (i.e., site-specific informed consent, study tools/worksheets, investigator contracts, and site payments).
- Oversight and management of CRO to ensure successful conduct of the clinical trial by managing daily study activities to ensure data integrity and quality.
- Communicating with study sites, proactively recognizing problem situations, and informing team members to enable issue resolution.

Qualifications:

- Bachelor's degree or higher in life sciences, health sciences, nursing, pharmacy, or other related field.
- 5 or more years of clinical research experience in industry settings.
- Experience working on large, global studies with multiple vendors involving management of

submission timelines and associated processes.

- Demonstrated experience in the identification of emerging risks and the ability to collaboratively champion solutions within a multi-disciplinary drug development team to help resolve challenges is required.
- Solid project and vendor management, analytical and problem-solving skills.
- Knowledge of GCP/ICH Guidelines for clinical studies.
- Ability to work independently and take initiative in a fast-paced work environment.
- Excellent verbal and written communication skills.
- Competent computer skills including Microsoft Office.
- Familiarity with clinical systems.

Travel Requirements:

- Requires availability for 5-10% domestic and international travel, including overnight and international travel on an as-needed basis.