75 State Street, Suite 1400, Boston MA 02109 USA

Position Title:	Clinical Trial Associate
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 Associate Position Overview:

The Clinical Trial Associate (CTA) actively participates 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 regulatory inspection readiness, in accordance with established protocols and under the general supervision of the Clinical Trial Manager (CTM).

Responsibilities:

- Work with Clinical Trial Manager, study teams, and Clinical Research Organizations (CROs) to support clinical study activities as defined by the clinical trial operating model.
- Provide support for essential daily clinical study activities, including regulatory inspection readiness, following established protocols under the general management of the CTM.
- Serving as the sponsor liaison to clinical sites during the activation process, as the study progresses, and during study close-out.
- Manage deliverables navigate changing priorities and communicate any changes.
- Coordinate and attend study team meetings; take, distribute, and file meeting minutes.
- Maintain and generate applicable study trackers (for example: patient enrollment and IRB approvals).
- Overall management of the Trial Master Files (internal and CROs) including managing set-up, maintenance, and periodic QC.
- Manage the Clinical Operations internal document filings and tracking.
- Participation in evaluation of clinical trial site locations.
- Traveling to sites as necessary to assist with site qualification, initiation, and close-out.
- Working with clinical site staff and investigators to obtain study data, ensure protocol compliance, and guarantee patient safety.
- Participating in regional and global conference calls and meetings to review progress of ongoing clinical trials.
- Reviewing incoming clinical data and preparing reports and presentations on the status of clinical studies.
- Helping to draft study manuals and protocol amendments as needed.
- Organizing and distributing study supplies and study-related documentation required for conduct of clinical trials.
- Perform departmental tasks.

- Professionally interact and communicate with internal departments (Legal, Regulatory, Safety, etc.), CROs, and external vendors.
- Perform developmental tasks with oversight of CTA Manager.

Qualifications:

- Bachelor's degree or higher in life sciences, health sciences, nursing, pharmacy, or other related field.
- 1 year or more of clinical research experience in industry settings.
- Knowledge of clinical trial methodology as well as the drug research and development process.
- 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.