195 Church Street, 14th Floor · New Haven, CT 06510 · (203) 304-2499

Position Description

Job title	Clinical Research Associate	**Date:**	June 2022
Reports To:	VP, Clinical Operations	**Department:**	Clinical Operations
Location:	New Haven, CT	**Classification**	Non-Exempt

Position Summary

The Clinical Research Associate (CTA) is responsible for providing general administrative support to Clinical Operations team in the execution and management of various clinical trials. This individual will perform routine duties associated with document management and submission to the Trial Master File, as well as assisting with the activities of the study team and associated vendors. The CTA works under direct supervision on tasks that require minimal discretion.

The CTA is responsible for performing activities in compliance with applicable Corporate and Clinical Operations Policies, Standard Operating Procedures and Work Instructions.

Responsibilities and Essential Functions

- Assists in the preparation and development of study related documents as applicable (e.g. study reference materials, protocols, informed consent forms and guidelines).
- Routes documentation for appropriate signage.
- Obtains, reviews, processes, and tracks study related documents.
- Prepares and maintains site manuals, reference tools and other documents.
- Updates enrollment status for assigned trials and helps to develop and maintain tracking tools.
- Assist with routine communication to study sites and broader study team (Vendors including Clinical Research Organizations (CROs) and support functions).
- Organizes, prepares reports, prioritizes and summarizes data, materials, and information for projects, as directed per schedule and ad hoc requests.
- Maintains, updates, and inputs clinical tracking information into databases.
- Tracks incoming and outgoing clinical and regulatory documents and updates for investigator sites, studies, project team, or client.
- Supports the daily maintenance of Trial Master File (TMF) or Electronic Trial Master File (eTMF), as required for project and department needs.
- Prepares, ships and manages inventory of study related supplies.
- Assists in the preparation of materials for meetings and training sessions for team members, site staff, and clients as needed.
- Assist in department in preparation for internal and external audits.
- Coordinates project meetings, prepare agendas and takes minutes.

- Performs other duties as assigned.

Qualifications and Experience

- Bachelor's degree or equivalent;
- 2-3 years of clinical experience in pharmaceutical, biotechnology or medical device company including CRO, a plus;
- Excellent command of spoken and written English;
- Strong computer skills working with Microsoft Office Suite (Word, Excel, PowerPoint, Outlook and Microsoft Project);
- Outstanding organizational skills;
- Team player with excellent attitude and excitement to cultivate strong cross functional relationships;
- Document change tracking & version control experience, a plus;
- Ability to develop and maintain a basic working knowledge of relevant protocols.