Clinical Trials Lead

Position Summary:

The Clinical Trials Lead assists in the implementation of study level processes and associated activities for Trevi's clinical trials. This individual is expected to operate with a high degree of independence and is responsible for overseeing and managing Phase 2 and Phase 3 clinical trials from study start-up to study close out. The CTL is accountable for the study timelines, day-to-day vendor oversight and ensuring study conduct is in accordance with Trevi's Standard Operating Procedures (SOPs) and ICH/GCP. This role includes managing and oversight of Clinical Research Organizations (CROs) and other service providers. They are responsible for contributing and driving ongoing process improvement initiatives and developing successful working relationships with clients (sites, vendors, ancillary departments). Working with clinical operations to ensure integrity of the clinical data and Investigator compliance with protocols. This position reports directly to the VP, Clinical Operations.

Duties and Responsibilities:

Study-start-up documentation and activities, site management, facilitating subject enrollment, field monitoring, and study follow up.

Coordination and management of Contract Research Organizations (CRO) and other third-party vendors (such as central labs, e-COA and IRT vendors, specialty labs, etc.)

Provides consistent, regular oversight of CRO and vendor performance including monitoring and site management; co-monitoring of assigned CRAs as needed and ensures studies are conducted under GCP and ICH Guidelines.

Operational management of global Phase II-III studies within various indications and/or therapeutic areas.

Responsible for ensuring that the conduct of these studies delivers against contracts and in accordance with study protocols, FDA regulations, Good Clinical Practice (GCP) Guidelines, and company timelines.

Works with the VP of Clinical Operations and Clin Ops team to ensure clinical trial activities are progressing according to forecasted patient enrollment and helps implement strategies necessary to maintain trajectory of forecasted project or company deliverables; may report study metrics to senior and executive management.

May attend CRO or other vendor meetings such as project kick-off and investigator meetings.

Obtain and review site visit reports and other supporting documentation from CRO study monitor(s) as part of the oversight of the study. Contributing member of various study and program teams; Works closely with the study team to support operations and execution of clinical protocols, and study plans for Trevi's company portfolio.

Obtain and review all pertinent study documents from the CRO for study initiation, execution, and close out as required.

Participate in the drafting, editing and review of clinical SOPs as required.

Travel may be required up to 25% in support of clinical study activities. Additional travel up to 15% may be required if necessary for co-monitoring or for study start up activities such as Investigator Meetings.

Additional Duties as required.

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skills, and/or abilities required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience

Minimum of a bachelor's degree in a science or health related field, such as chemistry, nursing, health care administration or health care management.

Minimum of 8 years of relevant clinical trial and operations experience required. Biotech/Pharmaceutical industry experience preferred. Must have prior experience with Phases 2 trials. Phase 3 experience is preferred.

Management experience including outsourcing to Contract Research Organizations (CROs) and other vendors with strict timeline management experience.

Working knowledge of US FDA CFR and GCP/ICH guidelines applicable to conducting clinical trials.

Working knowledge and direct experience with protocol and clinical drug development processes, study planning, clinical monitoring, and report reviews.

Competencies

Able to read, comprehend, write, and speak English fluently.
Excellent written and verbal communication and interpersonal skills. Able to communicate complex information clearly and succinctly, both in writing and orally.
Strong influencing, negotiating and problem-solving skills, including across functional, geographical and cultural boundaries.
Excellent problem-solving ability, able to lay out a strategic vision for a team, detail oriented, excellent organizational skills, ability to multi-task, re-prioritize duties, and work efficiently in a fast-paced matrix environment.
Proficiency in the management and oversight of clinical trial management, monitoring duties including site monitoring, tracking, working with clinicians to ensure adherence to protocol, FDA and GCP guidelines, initiations and close out visits.
Sensitivity to the needs of diversified ethnic groups. Must be able to build relationships and work collaboratively with all levels of individuals across the organization and externally.
Must be highly detail-oriented and have excellent organizational and time management skills.
Ability to multi-task, manage and prioritize various and differing projects, as well as work effectively toward numerous deadlines.
Model of integrity, professionalism, and confidentiality.
Above average computer skills, including Microsoft Office (Word, Excel, OneNote, PowerPoint, Outlook), Zoom and Internet.
Ability to work independently and in a team environment to contribute to the achievement of program objectives.

PHYSICAL AND VISUAL REQUIREMENTS:

While performing the duties of this job, the individual is regularly required to use computers and office equipment, manipulate documents, work in an office environment and in clinical settings. This position requires the ability to primarily work remotely and travel regularly up to 40% of the time in

support of clinical study activities. The individual may experience prolonged periods of sitting. The employee may occasionally move materials up to 15 pounds.

Note:

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Trevi reserves the right to modify, change or add to the position's job duties and responsibilities as business needs may require. This document does not create an employment contract, implied or otherwise, other than an "at will" relationship.

Trevi Therapeutics, Inc. is an Equal Opportunity/Affirmative Action employer including protected Veterans and individuals with disabilities. Trevi considers applicants for employment without regard to, and does not discriminate on the basis of, an individual's sex, race, color, religion, age, disability, status as a veteran, or national or ethnic origin; nor does Trevi discriminate on the basis of sexual orientation or gender identity or expression.