Esperion
The Lipid Management Company

Company Overview

Esperion is a small company doing big things. Our innovative team of lipid management experts is committed to leveraging its understanding of cholesterol biosynthesis to develop innovative therapies for the treatment of patients with elevated low-density lipoprotein (LDL-C). At Esperion we are passionately committed to bringing complementary therapies to the hypercholesterolemia space that address unmet patient needs in a way that is "patient-friendly, physician-friendly and payer-friendly."

Esperion's corporate headquarters are located in Ann Arbor, MI. The Company offers a competitive salary including a performance-based bonus program and stock-based compensation, a comprehensive benefits package including a 401(k) matching plan and health insurance, and paid time off and holidays.

Position Title: Senior Clinical Research Associate

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Assist in all trial management activities within Clinical Development and Operations with minimal supervision.
- Provide support to collaborating departments where needed (e.g. Quality Assurance, Regulatory, Pharmacovigilance)
- Review monitoring reports and correspondence generated by CROs for quality control and report issues to the team in accordance with the trial specific Quality Oversight Plan
- Create review and assess trial management and monitoring plans.
- Review CRFs, study tools, presentations and site communications
- Assist with protocol development, research reporting, and regulatory submissions
- Participate in investigator recruitment activities including identification and contacting of potential investigators; conduct pre-study site visits to assess the willingness and suitability of potential clinical sites
- Schedule and conduct on-site initiation, monitoring and close-out visits during clinical studies as indicated, ensuring adherence to the study protocol, accurate data collection and adherence to all local, national and U.S. Food and Drug Administration (FDA) regulations and international regulations, where applicable, according to GCP and ICH guidelines and SOPs.
- Track patient accrual, screening and enrollment information from sites. Promote patient enrollment at clinical sites as needed to achieve enrollment projections.
- Oversee and coordinate document flow and ensure quality control and reconciliation of the electronic Trial Master File for the assigned trial.
- Communicate study-specific information to/from trial sites, documents communication with study site/ team and escalates issues to team.
- Review clinical study data, adverse event reports and ensures timely reporting and resolution.

**additional duties and responsibilities not listed here may be required*

Qualifications (Education & Experience)

- BS in science, healthcare or another relevant discipline, with minimum of 5 years monitoring experience in pharmaceutical/biotechnology or CRO industry required.
- Thorough understanding of the clinical operations and regulatory process. Extensive experience with compliance issues and strong understanding of FDA regulations, GCP and/ SOPs in pharmaceutical, or biotech environment.
- Experience assisting trial management activities in globally is required.
- Experience working within the cardiovascular therapeutic area required.
- Domestic travel required, about 50%.
- Outcomes trial experience preferred.

All qualified applicants are requested to submit a cover letter and CV via email to hr@esperion.com.