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: Director, Clinical Operations

Preferred Location: Remote – US

Essential Duties and Responsibilities*

- Provide operational leadership to internal and external resources for late phase clinical trials to achieve program and company goals.
- Responsible for management and oversight of Contract Research Organizations (CROs)/vendors.
    - Lead CRO operational teams in the generation and delivery of quality recruitment plans and risk mitigation strategies.
    - Monitor trial progress; ensure active management and implementation of risk mitigation strategies and engagement of CROs.
    - Continued assessment of CRO resources and resolving CRO performance issues.
    - Oversee study management compliance activities and ensure inspection readiness.
- Effectively manage clinical operations activities.
    - Lead an operational team to analyze and deliver quality feasibility of clinical programs and protocols.
    - Ensure the collection of high quality clinical data; support and/or participate in the analysis of clinical data.
    - Develop clinical trial forecasts for budget based on resource requirements
    - Responsible for oversight of clinical drug supply; provide drug supply forecasts based on clinical trial requirements
    - Serve as the Subject Matter Expert (SME) on study protocol and operations and ensure proper training and education to internal and external resources.
    - May develop and manage internal and external clinical site monitoring activities for clinical trials on a global level.
- Effectively communicate clinical trial updates to the VP of Clinical Operations, Executive Leadership, and other appropriate functional groups.
- Work in a collaborative manner with cross-functional personnel to accomplish agreed upon deliverables by driving organizational best practices.
- Contribute to establishing study timelines and critical milestones

- Champion the implementation and use of harmonized, consistent processes and excellence in study management deliverables related to cost effective, timely and high quality clinical trial data.
- Participate in interdepartmental scientific and medical activities specific to implementation and conduct of clinical protocols.
- May manage clinical operations colleagues, consultants and CROs in variety of roles.

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

Qualifications (Education & Experience)

- Bachelor's and/or Master's degree in a scientific discipline; or equivalent combination of education and applicable experience.
- 10+ years of clinical trial operations experience in the pharmaceutical or biotechnology industry and a minimum of 5 years of experience in a project-lead or leadership capacity.
- CRO oversight experience required.
- Experience assisting global clinical trial activities required.
- Experience working within the cardiovascular therapeutic area required.
- Experience with patient retention is a plus.
- Experience in study management, monitoring, and pharmaceutical business.
- Working knowledge of the processes required to operationally execute clinical trials.
- Strong understanding of FDA regulations, GCP, ICH guidelines and clinical research SOPs.
- Demonstrated capability to proactively manage vendor-supplied resources including experience in site monitoring.
- Experience with protocol development is preferred.
- Experience interacting with internal and external stakeholders.
- Effective verbal and written communication skills.
- Ability to be flexible with changing priorities and work within a fast paced environment.

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