Position Specification
Lead Clinical Research Associate (LCRA)

Company Overview

Saol Therapeutics (pronounced "Sail") is a specialty pharmaceutical company focused on providing therapies to patients with unmet medical needs. The company has a strategic emphasis on CNS Disorders and Rare Disease therapeutic areas. Our seasoned management team has a broad range of experience in commercialization, acquisition, licensing, formulation and product development. We are a dedicated group of professionals who have committed our life's work to developing and bringing high-value, much-needed drugs to market. We are looking for highly-skilled individuals who are patient focused, passionate, ethical, team-oriented, and who want to help build a company that will make a difference in people's lives.

Location

Roswell, GA (US Headquarters)

Role Overview

The Lead Clinical Research Associate is responsible for assigned aspects of clinical research management of CRAs and site management in accordance with applicable Standard Operating Procedures (SOPs) and the International Conference on Harmonizations' (ICH) guidelines for Good Clinical Practice (GCP). The Lead CRA will assist and support Clinical Study Management (CSM) with study management and oversight activities.

The Lead CRA will be responsible for a few sites and will oversee CRA activities in relation to the protocol, regulatory compliance, data reliability, and the proper care and treatment of test subjects. The Lead Clinical Research Associate represents the organization in a professional and collegial manner.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Assist CSM in planning, tracking and driving start-up activities and activation timelines to meet study goals.
- Assist CSM to collect, track and ensure completeness of all essential regulatory documentation from site from study start-up through close out.
- Oversee and manage CRA team, reports and study sites from start up to close out and report issues to CSM.
- Ensure compliance with standard protocol and regulatory and ICH GCP obligations in assigned aspects of clinical site monitoring, such as site initiation, routine monitoring, maintenance of study files, study close out, and retrieval of study materials
- Complete on-site and remote monitoring activities in compliance with the Clinical Monitoring Plan, including source document verification, as required.
- Ensure the integrity of data and that the study is conducted in compliance with approved protocol, GCP, applicable regulations, and internal SOPs
- Perform key risk assessment and management responsibilities throughout the project, including key risk indicator and site health analysis, site process evaluation, and project escalation.
- Participate in audit preparation and follow-up activities, as needed.
- Verify the protection of study participants by informed consent procedures and protocol requirements that follow appropriate regulations.
- Verify proper management and accountability of Investigational Product.

- Write and submit reports of investigational site findings and update applicable tracking systems, as required; escalate observed deficiencies and issues as appropriate.
- Manage essential documents as required by local regulations and ICH GCP before, during, and after a clinical study; assist with resolution of investigational site/data queries
- Weekly follow-up with sites
- Ability to monitor remotely

KNOWLEDGE AND SKILL REQUIREMENTS:

- General knowledge of regulatory requirements & GCP
- Ability to multi-task and deal with shifting priorities
- High proficiency with full Microsoft applications
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; accurate and detail-oriented
- Experience with electronic EDC and TMF and other clinical research electronic systems

PREFERRED SKILLS AND EXPERIENCE:

- Bachelor's degree in a life science-related field, a registered nurse (RN) certification, or equivalent experience that demonstrates the experience of clinical research field for at least 4 years.
- 4 years' experience in a clinical trials research environment required
- Valid driver's license required

Travel Requirements

- Ability to travel required. Anticpated travel 20-30%.

Successful Candidates Demonstrate Saol's Values

Trustworthy – We believe that the foundation of trust is truthfulness, transparency and fairness. These principles will be the basis for all our interactions.

Focused on Patients – We will anchor our decisions with full consideration of their impact on our patients, believing that in doing what is right for them serves a higher purpose.

Passionate – We enjoy working hard, but are not one-dimensional, being curious about the world around us and striving to be continuous learners who surround ourselves with others who inspire and challenge us.

Nimble – We embrace new and promising opportunities while adjusting quickly and efficiently to the inevitability of change.

Entrepreneurial – We create value through our focus on providing solutions, drive to deliver results, and our ability to work together in solving business challenges with integrity.

Compensation

Saol Therapeutics is prepared to offer a competitive salary, bonus, and equity, as well as career advancement opportunities.

Apply or Learn More: Call and/or email resume to: HR@saolrx.com