Position Specification
Clinical Trial Assistant (CTA)

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 Clinical Trial Assistant (CTA) will support the project study team, during set-up, development and conduct of clinical research trials. The role will provide the necessary support to ensure successful implementation of all stages of a clinical trial, inclusive of start-up, execution, and closeout activities.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- The Clinical Trial Assistant will support activities related to clinical research, meeting minutes, email follow-up, regulatory review, filing and site contact follow-up on activities overseen by the Clinical Study Manager (CSM).
- Coordinate preparation and submission of protocol, consent and related study documents for IRB review and approval under direction of CSM.
- Assist in the preparation and review of study documentation under direction of CSM.
- Utilize tracking tools and monitor the progress of clinical trial elements including patient recruitment, trial related supplies, and trial documentation.
- Interface with clinical sites in the management of study materials and supplies, inclusive of ordering, tracking, storage, distribution, reconciliation and destruction of materials (where/as applicable).
- Review and file study and PV documentation and related archival systems and processes (e.g., Trial Master File, study tracking tools, PV, archives).
- Track and remind team of SOP documentation.
- Assist in the preparation and implementation of required SOPs under direct super vision of CSM and Safety Manager.
- Liaise with investigators and site staff to ensure distribution of study documentation inclusive of regulatory documents and safety data.
- Liaise between the study team members, CRAs and investigator sites and provide support with monitoring visit preparation and conduct, or related site Regulatory inspections, in an assistance capacity.
- Communicate and develop relationships with study sites, obtain regular updates specific to enrollment/recruitment status, provision and procurement of required trial documentation, fulfillment of study supply requests, study related training and other activities as required.
- Assist in the organizing of Investigator study meetings, meeting materials, training documents, agendas and minutes for study meetings under direction of CSM.
- Create tracking tools to assist in management oversight of financial clinical elements, including tracking of Investigator and vendor payments and periodic management reporting of same under direction of CSM.
- Maintain, and reconcile study Trial Master Files and ensure files are in a state of audit readiness.

- Assist with conduct of GCP monitoring and related audit activities (could increase travel requirements on periodic basis), under direction supervision of CRA or CSM.
- Provide administrative support to ensure the most effective and efficient conduct of all clinical trials.
- Perform other responsibilities as may be required by Saol, consistent with a growing, dynamic company.

KNOWLEDGE AND SKILL REQUIREMENTS:

- Strong organizational skills, detail oriented and able to effectively manage multiple tasks in a fast-paced environment and work independently.
- Strong oral and written communication skills.
- Proficient in the use of Microsoft office products, inclusive of Word, Excel, PowerPoint and Outlook.
- Ability to be flexible and adaptable in the face of evolving organizational priorities.
- Strong interpersonal skills and ability to work effectively with small teams with a wide range of varying stakeholders.
- Solid working knowledge of ICH GCP guidelines and applicable regulatory requirements.

PREFERRED SKILLS AND EXPERIENCE:

- 2 years' experience in a clinical trials research environment required
- Valid driver's license required

Travel Requirements

- Ability to travel, both domestically and international as needed. Anticipated travel is 5-15%.

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