Position Specification
Clinical Study Manager

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 spasticity and neurologic 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, Georgia

Manager

Director, Clinical Operations

Role Overview

The Clinical Study Manager will support Clinical Operations and Development activities related to clinical trial activities for products in the Saol development pipeline. The role will provide the necessary coordination, management and oversight to ensure successful implementation of all stages of a clinical trial, inclusive of start-up, execution, and closeout activities. Additionally, the Clinical Study Manager will provide the required support for other cross-functional development team members as required.

Responsibilities

- Capable of independently managing and supervising the operational aspects of clinical trials sponsored or supported by Saol Therapeutics.
- Provide management and oversight responsibilities for all external vendors involved in the conduct of clinical trial activities.
- Oversee the day-to-day clinical trial execution activities, ensuring conducted in accordance with Good Clinical Practice (GCP).
- Contribute to the development of protocols, consent forms and other key study documents.
- Contribute to development of study timelines and management of day-to-day study activities to ensure adherence to study timelines.
- Assist with the management of study budgets and vendor activities directly associated with study budgets.
- Coordinate preparation and submission of protocol, consent and related study documents for IRB review and approval.
- Assist in the preparation and review of study documentation
- Create 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).
- Prepare and manage study documentation and development of archival systems and processes (e.g., Trial Master File, study tracking tools).
- Assist in the preparation and implementation of required departmental SOPs.
- 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 provides support with monitoring visit preparation and conduct, or related site Regulatory inspections.
- 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.
- 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.
- Develop, 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 (approximately 20% travel anticipated).
- Provide administrative support to ensure the most effective and efficient conduct of all clinical trials.
- Provide critical review of Clinical Study Reports to ensure accuracy and quality.
- Provide necessary support for planned regulatory submissions (e.g., INDs and NDAs).
- Perform other responsibilities as may be required by Saol, consistent with a growing, dynamic company.

Qualifications

- Minimum Bachelor's degree in the sciences (or equivalent experience), with advanced degree a plus.
- 5-7+ years prior experience working in clinical research at sponsor or CRO, with at least 2-3 years' experience in the management of conduct of clinical studies.
- Strong organizational skills, detail oriented and able to effectively manage multiple tasks in a face paced environment.
- 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.
- Travel: US and International as needed (approximately 20%)

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 development opportunities.

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