Head of Clinical Operations	 SCHOLAR ROCK

Company Overview

Scholar Rock® is discovering and developing a new class of biologic therapies to selectively target dysregulated growth factors in the disease microenvironment by modulating supracellular activation, resulting in therapeutic effects specifically at the source of disease.

Our proprietary technology has a unique capability for highly selective targeting of growth factors which play a fundamental role in regulating cell growth and differentiation. Modulating supracellular activation is relevant to a wide range of diseases including fibrosis, diseases of musculoskeletal systems, autoimmune diseases, and cancer.

Scholar Rock has a highly experienced management team with leaders who have helped to build successful biotech companies. The company was founded by distinguished scientists, Dr. Timothy Springer, PhD and Dr. Leonard Zon, MD, whose key discoveries in growth factor biology are enabling the company's therapeutic approach.

Scope:

The Head of Clinical Operations will play a key hands-on leadership role to plan and execute all clinical development programs and studies. This will involve creating study plans, timelines and budgets, and managing all resources internally and externally. Primary responsibility will be for ensuring that clinical operational and development deliverables and timelines are met across all development programs.

Management of all aspects of study progress will include planning through to close-out, while assuring adherence to timelines and achievement of study goals while maintaining quality in accordance with FDA and EMA guidelines. The role is also responsible for the development and coordination of processes that will support global trials and study operations. This will involve providing leadership/influence across the company including impacted functional areas in support of trial operation goals.

This position reports to the Chief Medical Officer.

Responsibilities:

- Lead the evaluation, selection and management of Contract Research Organizations (CROs) and other external vendors to ensure successful clinical trial implementation and execution. Proactively manage CRO performance and promptly address any issues that may arise.
- Create, manage, and execute clinical operations and development programs, including study management, budget and timeline creation.

- Build strong relationships with Principal Investigators, KOLs, and patient advocacy groups.
- Collaborate with therapeutic thought leaders for feedback on study protocols and development plans.
- Lead cross-functional program development teams comprising external expertise and internal functional groups.
- Ensure optimal sponsor-site relationships by building strong relationships with site staff.
- Contribute to authoring clinical study protocols, informed consent forms (ICFs), clinical study reports (CSRs) and other clinical documents as necessary.
- Contribute to the development of clinical sections of regulatory documents such as Investigators' Brochures, briefing books, safety updates, IND submission documents, responses to Health Authorities' questions.
- Develop and ensure execution of activities outlined in various study plans (data management, safety management, and study communication plans).
- Partner with CMC/clinical suppliers to provide drug supply assumptions and contribute to design and packaging of supplies for clinical trials.
- Develop precise and timely written and verbal communications to provide senior management with ongoing status updates. Responsible for identifying and communicating risks, contingency planning and escalating potential threats to success in a timely manner.
- Develop mitigation strategies and corrective actions

Requirements:
A minimum of ten (10) years' experience in clinical operations in a pharmaceutical company, biotech firm, or CRO is required.

- Demonstrated effective planning and project management skills including the ability to prioritize, assess risk and develop contingency plans
- Experience with rare diseases is strongly preferred.
- Thorough understanding of country-specific, FDA (or equivalent), ICH and GCP guidelines as well as thorough understanding of cross-functional clinical processes including: data management, pharmacovigilance, biostatistics, medical writing, and regulatory affairs.
- Proven ability to lead a multidisciplinary team toward a successful outcome.
- Experience in developing effective relationships with key stakeholders.
- Thorough knowledge of clinical trial design, statistics, regulatory processes, and global clinical development processes.
- Understanding of drug development and program management from pre-IND through NDA is essential
- Excellent interpersonal, communication, negotiation and influencing skills.