Senior Director, Clinical Operations

Axial Biotherapeutics is a biopharmaceutical company harnessing the link between the human gut microbiome and Central Nervous System (CNS) to develop a new class of therapeutics that improves the quality of life for people with CNS diseases and disorders. In this exciting lab-based position, this scientist will apply their expertise in cell biology and biochemistry while collaborating closely with a passionate team in a dynamic environment to deliver important new medicines that help patients and their families.

Scope of Role

Reporting to the Chief Medical Officer, the Senior Director of Clinical Operations will be responsible for overseeing the strategy for implementation as well as execution of all Axial sponsored clinical trials within established timelines, budget and quality standards. In addition, the successful candidate will ensure the appropriate company infrastructure is in place to support the planned clinical trial programs for Axial's therapies. This individual will be responsible for leading all operational aspects of Axial's clinical trial programs. Finally, the person in this position is accountable for adherence to relevant regulatory requirements and company Standard Operating Procedures (SOPs) as appropriate.

Essential Duties and Responsibilities

- Ensures that external vendors are selected and managed to deliver within established timelines and budget. This also includes site qualification and initiation.
- Provides strategic and technical guidance to ensure that clinical trials are properly defined, planned and executed. Leads and directs the clinical operations team responsible for management and execution of all clinical trials. This includes but is not limited to, ensuring cost, quality and timeliness of multiple programs is met.
- Working in a matrix organization, ensures that study objectives are in line with the clinical development strategy and the overall corporate goals.
- Leads and directs the building of department infrastructure, including developing, training, and retaining the clinical operations team; ensures prioritization of activities and resourcing is in line with clinical development programs.
- Drives the creation of clinical operations Standard Operating Procedures (SOPs), systems, and processes across the trials; ensures compliance with regulatory and other applicable standards and guidelines.
- Builds collaborative relationships with key internal stakeholders including Clinical, Product Development, Program Management, Regulatory Affairs, IT, Legal, Finance departments, and project teams as needed to support clinical programs.
- Collaborate with KOLs for feedback on study protocols and development plans.
- Fosters a highly collaborative culture and serves as a leadership role model within the company and with external stakeholders.
- Contributes to business development activities as needed. This may include providing critical due diligence and analysis of programs.

Qualifications

- Minimum education: M.S. /B.S in life sciences, scientific or other relevant discipline.
- 10+ years of strong hands-on experience leading global clinical trials execution, preferably in CNS conditions.
- Experience with Phase 1-3 trials
- Proven ability to build strong relationships with external partners, CROs, and vendors including extensive experience managing contracts and clinical finance activities.
- In-depth, working knowledge of Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines.
- Ability to work independently and collaboratively in a fast-paced, matrixed, team environment consisting of internal and external team members.
- Analytical thinker with excellent problem solving skills and the ability to adapt to changing priorities and deadlines.
- Excellent verbal and written communication skills.