Full Job Description (Contact: Kevin Li, Kevin_Li@topalliancebio.com)

Position Title: Clinical Trial Manager (Full-time)

Position Location: On-site/Remote

Position Reports To: Executive Director, Clinical Operations

Position Description: The Clinical Trial Manager is accountable for the day-to-day operations of assigned clinical trials, including start-up, conduct and close-out activities. This position will perform required job duties with guidance to ensure the trial is conducted in compliance with the study protocol, SOPs, and applicable regulatory requirements.

Essential Responsibilities:

- Serve as the primary contact for managing protocol execution, including oversight of the CRO, service providers, and consultants that are involved in a clinical trial
- Coordination of cross-functional internal and external study team members (biostats, clinical pharmacology, data management medical monitors) to ensure initiation and execution of the clinical study deliverables within approved budget and timelines
- Establish study milestones and ensure accurate tracking and reporting of study metrics and timelines
- Ensure clinical trials are managed and executed in accordance with ICH GCP, regulations, the protocol, and company-specific SOPs
- Assist in preparation and review of clinical documentation such as protocol, informed consent, Investigator Brochure, Clinical Monitoring Plan, Project Plan, case report form, statistical analysis plan, clinical study reports, and other study level documents
- Ensure that the Trial Master File (TMF) is set up and maintained appropriately throughout the trial, including periodic reviews
- Participate and respond to Quality Assurance and regulatory authority inspection audits Responsible for and participates in service provider selection process as a part of outsourcing activities.
- Responsible for the selection and study specific training of CRO study staff, monitors, investigational sites, and service providers In conjunction with legal group, facilitate the development of clinical trial agreements and other relevant documents
- Manage clinical trial budgets, providing ongoing financial reporting and projections Perform and manage data review process on an ongoing basis
- Negotiate and finalize site contracts and budgets
- Perform site visits including oversight, site qualification, initiation, monitoring and close-out visits, as needed
- Plan and coordinate Investigator Meetings
- Risk management and mitigation including prioritization of competing tasks and issues to ensure program/study objectives are successfully accomplished
- Awareness of disease / treatment landscape, changing regulations and guidance with ability to assess the impact on clinical projects and make modifications as necessary
- Ability to creatively approach challenges and problem resolution to optimize the conduct of clinical trials

Qualifications:

- Demonstrated experience in core and technical aspects of initiating and managing phase 1-3 clinical trials
- Demonstrated experience in management of CROs and vendor selection

- Demonstrated willingness to be hands-on and perform tasks within tight turnaround time
- Possessing excellent interpersonal and communication skills, with developing leadership attributes
- Demonstrated experience in the application of US and Global Regulations and Guidance (SOPs, ICH-GCP, FDA-CFR, ethical standards)
- Experience in data collection, monitoring, cleaning and analysis throughout clinical development (phase 1-3)
- Proficiency in Microsoft Office (Word, Excel, PowerPoint, Outlook), electronic TMF, and electronic clinical technologies
- Able to multi-task in a fast-paced environment
- Able to build strong cooperative relationships with coworkers
- Author complex documentation with minimal supervision
- Possess a high degree of attention to detail
- Previous employment at a pharmaceutical or biotech company or CRO

Education:

- Bachelor's Degree, Master's Degree or higher in science, nursing, medical field, or business management. An Associate's Degree /RN or equivalent with relevant years of experience is acceptable.
- Typically an average of 6+ years in the pharmaceutical industry is required, including but not limited to 2 years overseeing trial management.

Language skills:

- Superior written and spoken communication skills in English
- Ability to clearly communicate complex issues, observations and resolutions to management

Reasoning ability:

- Exercise judgment within broadly defined procedures and policies in selecting methods, techniques, and evaluation criteria for obtaining solutions
- Work on complex problems where the analysis of situations or data requires in-depth evaluation and propose possible solutions
- Work with minimal supervision both independently and as part of a team
- Proactively foresee and solve problems and commit to a high level of service