Klus Pharma Inc. Study Manager/ Associate Director, US Clinical Operations

Klus pharma is seeking a Study Manager/ Associate Director, US Clinical Operations who works independently with minimal guidance and direction, who assists in the planning and conduct of Klus clinical studies. Ensures compliance to study protocol, domestic and international Good Clinical Practices, applicable regulatory standards, and Standard Operating Procedures. Able to solve complex problems; considers alternative or new perspectives using existing tools and standard processes. Focus is on the development and management of a subject screening committee to ensure trial enrollment goals are met. May contribute to developing other study related materials; May also provide oversight of additional vendors and committees.

This opening will suit those with a proven track record as a Study Manager with strong flexibility.

Primary Job Function Responsibilities :

- Matrix management of functional areas and/or study vendors to ensure clinical study(ies) execution occurs per timelines
- Escalates performance issues to management with possible solutions
- Assist in the coordination of activities of a cross-functional team to ensure the initiation, conduct and completion of one or more clinical
- Ensures studies are done on time and within budget. This may include assigned study region(s)
- Prioritize activities to ensure study goals are met. This may include activities of site monitors from their assigned region(s)
- Lead study activities such as protocol preparation, investigator selection, site budget/contract development, investigator meeting, vendor selection, CRF design, specification review/approval, and monitoring oversight
- Monitor or Co-monitor sites with or without CROs
- Assist in the processing of SAE information received from investigators including review, clarification and interactions with monitors, sites and sponsor.
- Lead the initiation, maintenance and close out activities of multi-center and/or external site studies in accordance with the protocol, GCP, and relevant SOPs
- Proactive management of screening and recruitment activities, support site personnel with strategies to ensure enrollment is on target. Maintain enrollment logs regularly.
- Pro-active identification and mitigation or resolution of issues affecting proper conduct of the trial, including escalation to management and other team members as appropriate to ensure proper resolution.
- Provide and support initial and ongoing training to site personnel as needed
- Ensures compliance with protocol and all regulatory policies, procedures and/ or guidelines during clinical studies by training/guidance of investigators/study coordinators, and follow-up of corrective actions.
- Ensures validity of study by identifying/resolving discrepancies and obtaining missing data and tracks study enrollment activities and more complex components of the trial.
- Contributes to developing and writing clinical protocols, case report forms, committee charters, and other study aids for investigational products by addressing issues by interacting with appropriate personnel.
- Maintains expertise in regulations for applicable geographies and types of studies. Serves as a resource for clinical trial regulations.
- Mentors and trains new employees. Demonstrates leadership within their organization and provides general leadership direction.
- Seeks out opportunities to demonstrate skills and knowledge base to senior leaders.

- Ensures timely collection of study documentation by obtaining, maintaining and controlling all necessary records and documentation according to procedures and regulations.

Supervisory/Management Responsibilities
Position Accountability /Scope

- oversight and guidance
- This position will report into Director, US Clinical Operations
- This position may develop study budgets with a manager's final approval and approve payments to sites/vendors after comparing invoice against an executed contract.

Qualifications
Minimum Education

- Bachelor's degree or equivalent is required, typically in nursing or scientific field.

Minimum Experience/Training Required

- Must have 5 - 15 years of Pharma-related/ clinical research related experience
- On-site monitoring experience conducting SIVs, IMVs, and COVs highly desired
- Must have demonstrated a high level of core and technical competencies
- Possesses good communication skills
- Competent in application of standard business procedures (SOPs, ICH, Global Regulations, Ethics and Compliance)
- Preferred exposure to study initiation through study completion
- This position requires candidates to be detailed-oriented, computer proficient in a Windows environment and possess superior interpersonal and organizational skills
- Strong public speaking skills
- Excellent oral and written communication skills
- Excellent problem-solving and decision making skills
- CCRA or PMP is a plus
- Oncology experience is desirable

Primary Location: North America - US Home-Based
Job: Clinical Project Management
Schedule: Full-time
Travel: Yes (up to 40%)
Employee Status: Regular

Please send your resume to Yulian Zhang:

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