Clinical Program Lead (CPL)

Join our team! At Mustang Bio we are driven by people. The patients we serve and the team we are building are the driving forces behind our mission to deliver life-changing first-in-class cell and gene therapies to patients with genetic diseases and aggressive forms of cancer.

Summary of Job:

The Clinical Program Lead (CPL) is responsible for managing Clinical Operations activities and providing functional supervision for Clinical Operations staff within their assigned Clinical Program(s) as determined by Clinical Operations Leadership. The CPL conducts required tasks in collaboration with Clinical Project Managers (CPMs), Clinical Research Associates (CRAs) and the Clinical Trial Associates (CTAs) as well as with other members of the cross-functional Clinical Program Study Teams. Responsible for representing Clinical Operations at the Clinical Program level and for managing Clinical Operations activities as assigned with an entrepreneurial approach that requires the ability to multi-task on a wide spectrum of activities with an overall external focus.

Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following within the scope of their assigned Clinical Development Plan:

- Oversee clinical study and site management activities including trial timelines, budgets, resources and vendors.
- Supervise CPMs and CTAs as assigned in collaboration with the Therapeutic Area Lead. Assign short to mid-term responsibilities. Identify training needs to foster high level of performance, support career development through personal develop plans in conjunction with personnel's manager. Proactively manage performance issues. Establish key performance indicators in alignment with department and company objectives.
- Ensure effective study plans are in place and operational for each trial and work proactively with the Clinical Study Teams to set priorities in accordance with applicable study plans, company standard operational procedures (SOPs), ICH/GCP guidelines and regulatory requirements.
- Determine Clinical Operations FTEs required to efficiently execute Mustang Bio clinical trials and provide regular updates and recommendations to DCO regarding resource management.
- Support the VP, Clinical Operations and DCO in the development of the annual Clinical Operations budget and hiring plan.
- Ensure potential study risks are escalated to the attention of the Therapeutic Area Lead when appropriate.
- Develop and implement training and supporting operational documentation in collaboration with the DCO (SOPs, WIs, tools, etc.) for CPMs and CTAs.
- Develop clearly defined strategies and lead or contribute to assigned global, cross-functional interdisciplinary, high priority initiatives and process improvements.
- Cooperate across all Mustang Bio relevant business units and maintain effective working relationships with interfacing groups.
- Provide Clinical Study Management support on trials when appropriate and as determined by the DCO.
- Other duties as assigned

Vendor Management (within assigned Therapeutic Area):

- Oversee Mustang Bio Clinical Operations vendor relationships for studies as appropriate
- Ensure appropriate vendor management activities are occurring across all studies
- Escalate any vendor issues that may impact study or program
- Contribute to vendor selection decisions as appropriate
- Ensure appropriate functional or cross-functional governance is in place for any vendors that support multiple studies or functions

Cross-Functional Representation

- Facilitate timely and effective communications from Mustang Bio Clinical Operations leadership to Mustang Bio Study Team staff, Sites, and Contractors including decisions and progress, as well as communicating significant decisions and issues (including those of any functional area sub-teams or committees) from Mustang Bio Clinical Sites, and Contractors back to Mustang Bio Leadership
- Contribute to the establishment of Clinical Development Timeline goals that are aligned with Corporate Clinical Development goals and that clinical sites and other functional teams are executing to optimally achieve those goals.

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required.

Education/Experience: Bachelor's required; Advanced degree preferred

- A minimum of 10 years of clinical operations experience, with increasing levels of responsibility, in the Pharmaceutical, Biotechnology, Medical Device and/or CRO industry is required.
- Five or more years of clinical program management experience at a sponsor or CRO company
- Prior line management experience is required.
- Prior monitoring/co-monitoring and clinical study management experience is required.
- Therapeutic experience in oncology and/or rare disease (preferred)
- Experience in cell and gene therapy a plus
- Experience in early phase trials (Phase I-II) and First-In-Man trials (preferred)
- Sets high standards for performance for both self and others. Strong achievement orientation
- Possesses the awareness and ability to apply the correct principles, ethics, and regulations to plan and conduct safe and effective clinical activities. This competency requires the organization of various resources to meet expected deliverable and deadlines.
- Anticipates study/process risks related to scope, approach, and subcontractor/vendors; applies risk assessment and mitigation techniques
- Displays insight in analyzing complex situation, considers various approaches and perspectives in addressing problems and makes timely decisions, anticipating their potential impact and using sound judgment
- Ability to understand strategic goals and meet the business needs of the company
- Develops and maintains productive relationships built on mutual trust with internal/external professionals
- Strong verbal and written communication and presentation skills

Knowledge, Skills and Abilities:

- Read, write and speak fluent English; excellent verbal, written and presentation communication skills
- Must have a thorough knowledge of clinical research concepts, practices, and FDA regulations and ICH Guidelines regarding drug development phases, clinical research and data management methods.

Work Environment: This is a high growth, fast paced small organization. The ability to be productive, flexible, and accountable in an intense work environment is critical to the success of the person in this role, the team and the program. Willingness and ability to travel domestically and internationally may be required, it is anticipated that this will be less than 20% of work time.