Executive Director/Vice President Clinical Operations

SUMMARY

The Executive Director/Vice President Clinical Operations is a key position responsible for all aspects of day-to-day Clinical Operations activities. The Executive Director/Vice President Clinical Operations will provide operational expertise and leadership within the Clinical Development group to ensure timely initiation, execution and reporting of clinical trials in accordance with GCP requirements to support licensure of products in the US and globally. This individual will work closely and collaboratively with colleagues within Clinical as well as cross-functionally with internal and external representatives of Regulatory, Quality, Biostatistics, Medical Writing, Project Management, Drug Safety, and other functions to ensure the execution of clinical studies on time and within budget. The ideal candidate will have ten or more years' experience conducting clinical trials in pharmaceutical, biotech or CRO industry, with seven or more years' direct experience in managing clinical insourced/outsourced services. This position requires leading and working hands-on with the Mustang team to ensure the effective design, execution and completion of all clinical trials, including phase I-IV Mustang-sponsored and Investigator-sponsored trials.

RESPONSIBILITIES

- Responsible for oversight and management of clinical studies including vendor management
  - Set study goals and timelines and manage internal and vendor resources and deliverables within timelines
  - Accountable for developing and managing overall study budgets
  - Provide regular updates to the Study Team and management as appropriate addressing any issues in a timely manner
- Own relationship with CROs and provide day-to-day direction/supervision to vendor teams
  - Oversight and quality management to ensure CRO meets timelines and budget
  - Oversee timely review of monitoring visit reports and appropriate identification, escalation and resolution of issues
  - Collect and communicate interim data for internal and external use as appropriate
  - Ensure an efficient CRO/vendor selection process from RFP through contract
- Accountable for ensuring accurate and timely data cleaning, including data listings review
- Lead protocol development/writing and study implementation
  - Lead interactions with CROs and investigators to refine and finalize protocols
  - Responsible for feasibility, investigator and site selection and selection of vendors
  - Conduct protocol and site feasibility assessments
  - Provide guidance on operational and logistical issues
- Lead the design and preparation of other study documents (including CSR, IB, study manuals, etc.)
- Lead the preparation of the clinical content of regulatory submission packages

EDUCATION & EXPERIENCE

- Advanced medical or science degree (MS/PhD) or equivalent experience in a scientific or healthcare discipline.
- Experience managing immuno-oncology studies is required

    - 12+ years of clinical operations and study management experience in oncology clinical and drug development.
    - Demonstrated experience leading multiple cross-functional study teams
    - Experience in project planning, and identifying and managing risk
    - Experience in setting and managing trial budgets, site selection strategies, clinical supplies management, sample management, conduct and monitoring of clinical studies
- 7+ years of experience leading a high performing clinical operations team including remote team members
- Ability to effectively utilize and mentor staff to develop their skills to ensure they remain challenged and engaged professionally
- Effective leadership of multiple cross-functional study teams
- Experience in selecting, managing and partnering with CRO's to deliver a broad range of CRO services
- Strong communication skills with both internal and external stakeholders, with the ability to harmonize cross-functional activities
- Ability to work independently in a fast-paced environment with minimal supervision
- Working knowledge of regulatory and ICH GCP guidelines
- Excellent presentation skills
- Anticipated travel up to 20%
- Experience with clinical trials involving CAR-T therapy or other adoptive cell therapy is highly desirable