**Title: Director Clinical Operations**
**Location: Worcester, MA**
**Reports to (title): Senior Medical Director**

**Overview**

The Director Clinical Operations will provide operational expertise and leadership within the Clinical Development Department to ensure timely initiation, execution and reporting of clinical trials in accordance with GCP requirements to support licensure of products in the USA and globally. The Director Clinical Operations 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.

**Specific Responsibilities**

- Actively participate in study protocol design and review and provide guidance on operational and logistical issues
- Facilitate the timely completion of study protocols/amendments and development/revision of electronic data capture databases
- Manage contracts with vendors, including Contract Research Organizations, from RFP through contract, and establish an efficient process for the development, review and approval of contracts
- Manage resource planning for each clinical trial and across all assigned clinical trials
- Contribute to the development, revision and approval of Clinical Study Reports, DSUR/PSUR and Investigator Brochures as appropriate
- Manage Clinical Operations team, CROs and ancillary vendors to ensure work quality, timeliness and adherence to budget
- Set expectations across groups/departments within the organization to ensure the timely setup, initiation, execution and reporting of interim clinical trial results to Data Management Committees, IRBs and health authorities and for the timely generation of data needed for Clinical Study Reports and integrated summaries of safety and efficacy
- Direct and manage development of initial and updates to Investigator Brochures
- Develop standards for reporting study progress metrics in line with Clinical Operations guidance and expectations
- Guide and actively participate in preparation and review of clinical dossiers including briefing documents for meetings with domestic and international health authorities, Investigational New Drug (IND) filings, Clinical Trial Applications, safety reports, clinical study reports and other ICH compliant sections of registration dossiers (e.g., BLA, MAA, NDS, etc.)
- Provide oversight of clinical trials to ensure that all adverse events or product safety issues are captured, reported and evaluated by appropriate Clinical personnel in a timely manner
- Develop clinical SOPs and support the design and execution of quality management plans consistent with GCP and other applicable government and regulatory agency standards
- Direct and manage Clinical Operations budget forecasting, monitor the budget against actuals and apprise Management of variances

**About You**

Advanced medical or science degree (MS/PhD) or equivalent experience. 10+ years industrial clinical research and operations management experience in biotech or pharmaceutical firms, with emphasis on management of clinical operations

- Extensive domestic and international experience in overseeing clinical operations ensuring compliance with GCP requirements

- Proven experience in managing Phase 1, 2 and 3 trials, as well as trials fulfilling post-marketing commitments; familiarity with registry studies is a plus

- Proficiency in managing and developing a staff of clinical operations personnel, contractors and CROs

**Competency Expectations:**

- Excellent listening, communication and interpersonal skills with the ability to foster team spirit
- Solid well-grounded experience in setup, execution and operational management of domestic and international Phase 1, 2, and 3 clinical trials across an array of therapeutic areas including studies for treatment of patients with rare disorders
- Extensive experience managing CROs providing laboratory, imaging, electronic data capture and data management services, in addition to experience working with drug safety service providers
- Experience producing clinical study reports with complete appendices, CRFs and electronic datasets
- Knowledge and experience in preparation of Clinical sections of INDs, CTAs, BLAs, MAAs, etc., including data needed for completion of sections in eCTD Module 1
- Outstanding skills in managing direct reports, CROs and others involved in clinical development activities to meet corporate objectives
- Ability to accurately project budgets and manage them across studies and projects
- Experience in mentoring staff to develop their skills and ensure they remain challenged professionally
- Proficient in use of electronic clinical database software and other programs such as Microsoft Office

**About Us**

Recent medical breakthroughs in cell and gene therapy have signaled a coming revolution in patient care for previously untreatable disease. Our multi-disciplined team at Mustang Bio is translating these breakthroughs into next-generation therapies for hematologic cancers, glioblastoma and rare genetic diseases. We expect to advance 2-3 new therapeutic candidates into the clinic annually and have developed the manufacturing expertise required to develop and commercialize these therapies on a broad scale.

We offer the opportunity to collaborate with a world-class team of cell and gene therapy experts in developing next generation medicines in areas of high patient need.


We are an equal opportunity employer and value diversity. All employment is decided on the basis of qualifications, merit and business need. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.