**Director – Clinical Operations**

Cranbury/Newark, NJ, US

Worker Category: Active - Regular full-time

Now is an exciting time to join Cornerstone Pharma, a leading late-stage Oncology rare disease company.

We are a company united by strong values – passion for patients, innovation, integrity, excellence, leadership, ownership, and teamwork. Our values reflect the way we strive to improve the quality of life for patients and are at the heart of our company’s success and future growth.

We continue to seek passionate, dedicated, and solutions-oriented people – and consistently ensure that our people develop their talent. If Cornerstone Pharma is to realize its vision, we need people who think innovatively and act with integrity.

We currently have an opening for a Director of Clinical Operations in our Cranbury/Newark NJ office.

In addition to developing its lead Cancer Metabolic molecule CPI-613® (devimistat) Cornerstone is looking to increase its breadth through co-development, partnering, and acquisitions.The Director of Clinical Operations at Cornerstone will lead the execution of global and/or local oncology phase 1-3 clinical studies, programs, or franchises in adherence to Good Clinical Practices (GCPs), appropriate Standard Operating Procedures (SOPs), Food and Drug Administration (FDA) regulations/EU Directive, and International Conference on Harmonization (ICH) guidelines. A key focus will be the oversight of and interactions with CROs and other external vendors and internal stakeholders to ensure studies are conducted according to the timeline, budget, and quality measures set forth by the Study team.

The Director will take responsibility for the clinical operational strategy and overall delivery of the clinical study (i.e., Delivery Lead role) and will represent Clinical Operations on the study team. This role will ensure timely study start-up, execution, and study management as well as the support of database locks consistent with study/program timelines across the studies under their responsibility.

This position may require line management responsibility of Clinical Study Managers, who are primarily responsible for the tactical execution of the study. This role will need strong functional management skills to support the ongoing development of staff as well as the ability to define appropriate resource models to support new and ongoing studies. In the absence of the Clinical Study Manager, the Director will be expected to take both strategic and tactical roles in order to deliver the study.

**Role and Responsibilities:**

* **Operational Strategy**
* Align with Clinical Operations on plans for successful implementation of studies
* Responsible for the management of compounds at the program and franchise levels
* May represent Clinical Operations on the Strategy and Portfolio or Clinical Sub Teams in their therapeutic area
* Ensure operational aspects are incorporated into CDP planning and individual protocols to facilitate the successful implementation of programs.
* **Clinical Operations**
* Ensure high-quality delivery of all studies for which they are responsible. This includes individual studies as well as programs or franchises
* When sitting on a study team, lead the study team to develop a cross-functional, integrated study plan and create an initial study budget. Review study feasibility assessments provided by the CRO(s), lead the CRO selection process, and provide input into ARO selection.
* Validate the study implementation plan provided by the CRO through to study close-out and CSR writing. Ensure the timing of the major study milestones and the associated budget meet the needs of the overall development plan agreed to by the Global Project Team (GPT).
* Lead site selection and site qualification discussions, kick-off meetings, and study team meetings
* Oversee the CRO and provide timely input to ensure that the study is executed according to the agreed project plan. Complete a study risk assessment and ensure mitigation and contingency measures are prepared and implemented. Actively assess potential risks to the study and propose mitigation plans.
* **CRO and Quality Oversight**
* Responsible for oversight of all CROs utilized within their therapeutic area. May represent Clinical Operations on the DS/CRO Joint Operating Committee.
* Work with Process Excellence and Risk Management to ensure oversight plans are in place for all studies falling under their responsibility
* Design, update and implement appropriate innovative and best-in-class procedures and SOPs related to clinical study oversight and execution
* Work with TMF Operations to ensure a state of inspection readiness for all TMFs and ensure quality expectations are met
* When sitting on a study team, responsible for the management of CRO(s) performance to ensure adherence to scope of work within timelines and budget at an overall study level
* Specifically, track major study milestones and monitor overall operational performance metrics through the life of the study
* Identify issues early and propose solutions. Whenever possible, resolve issues that have been escalated or if warranted, take issues to the appropriate governance committee.
* Create the budget at the study start-up and monitor the overall agreed budget against trial progress
* Work closely with internal and external stakeholders to ensure team awareness of the CRO scope of work (to minimize unwarranted change orders) and budget, so both can be managed appropriately

**Required Skills:**

* Education: BA/BS, MS or equivalent in a scientific discipline is preferred
* 5-7+ years of progressively more challenging work experience in Clinical project management in domestic and international clinical trials
* In-depth knowledge of regulatory regulations and ICH guidelines in drug development and approval with good experience in multiple FDA and EMA filings
* Good organizational and problem-solving skills, as well as the ability to evaluate resource needs
* Proficient at creating and communicating a clear vision among team members effectively aligning resources and activities to achieve functional area and/or organizational goals
* The successful candidate should be a results-oriented, team player with strong interpersonal and communications skills, capable of working collaboratively with colleagues
* Possess strong and influential leadership skills with a proven ability to lead internal

and external team members at all levels

**About Cornerstone Pharmaceuticals:**

*Cornerstone Pharmaceuticals, Inc. is a clinical-stage company and a leader in the growing field of cancer metabolism-based therapeutics. Cornerstone’s primary objective is to develop and commercialize innovative, highly selective, well-tolerated, and highly effective anti-cancer agents by selectively targeting the altered metabolism in cancer cells. Cornerstone’s first-in-class clinical lead compound, CPI-613®(devimistat), is being evaluated in multiple ongoing/completed Phase I, II, and III clinical studies. CPI-613®(devimistat) has been granted orphan drug designation for the treatment of Pancreatic Cancer, Acute Myeloid Leukemia (AML), Peripheral T-Cell Lymphoma (PTCL), Burkitt Lymphoma and Myelodysplastic Syndromes (MDS). For more information, visit* [*https://cornerstonepharma.com/*](https://cornerstonepharma.com/)