Job Description

Position: Vice President, Clinical Operations

Role description

The Vice President, Clinical Operations will be responsible for the strategic oversight, execution (within budget and timelines), compliance and day-to-day management of the clinical operations team, as well as CRO management for investigational and marketed products. She/he will identify and drive strategic initiatives for clinical trial process improvements.

Location

This role is located in Ann Arbor, MI

Hours

This is a full-time role

Responsibilities

- Primary leadership role for overall clinical operations strategy and execution of clinical trials
- Manage direct reports within the Clinical Operations line function across the US and EU (Lyon, France); ensure appropriate staffing of the line function to meet clinical deliverables
- Accountable for strategy around insourcing, outsourcing and management of strategic alliances with CROs and external partners
- Develops and implements a risk evaluation and mitigation strategy as it pertains to the conduct of clinical trials and key milestone deliverables
- Responsible for driving innovation and efficiencies in the execution of all clinical trials and adapting the right clinical operating model
- Lead the effort to develop and refine processes that govern all Clinical Operations and CRO activities, including vendor selection, operational systems and related SOPs (study planning, selection of study sites and investigators, tracking metrics, reporting, and conduct of clinical trials)
- Support the preparation and planning of study protocols, clinical study reports, as well as clinical operation components of submissions to regulatory authorities
- Monitor effectiveness of department SOPs/processes and performance against key quality metrics

Requirements

- A bachelors degree in Life Science is required, advanced degrees are preferred
- 10+ years' experience within clinical operations and 5+ years leading a clinical operations group
- Demonstrated ability to build, lead and run a best-in-class clinical operations team
- Experience managing all phases of clinical trials from IND through to post-marketing
- Demonstrated ability to lead the selection of CROs and vendors, put effective MSAs in place which include clear expectations around CRO performance, and establish plans that hold CROs accountable, on-time and on budget
- Expert knowledge of relevant FDA and EMA regulations, ICH Guidelines, GCP and other applicable regulations and a demonstrated ability to reduce these to good operating principles and practices
- Travel may be required up to 25% of the time, including some international travel
- Ability to work in a dynamic, matrixed environment while exhibiting honesty, trust, fairness, cooperation and flexibility

Reporting relationships

This position reports into the SVP, Development. There are three direct reports as well as additional management responsibility for external consultants, vendors and CROs. This role is a member of the Program Development teams and the Millendo Management team.