Position Title: **Clinical Trials Manager, II**

Reports to: **Associate Director, Director or Sr. Vice President, Clinical Operations**

Department: **Clinical Operations**

Updated: **April 26, 2018**

General Summary:

Responsible for managing the clinical operations function and personnel assigned to the planning, execution and data collection activities on assigned clinical projects

Principal Duties and Responsibilities:

- Participate on all project development teams
- Provide regular updates to senior clinical operations management on the implementation and progress of all clinical development projects
- Represent the Company externally in scientific, financial and business development communities
- Create study documents for multiple studies (budgets, timelines, template forms)
- Ensure that all studies are conducted in compliance with GCP, relevant SOP's & regulatory requirements
- Manage multiple phase 1-3 US and global studies and assure process consistency between studies
- Manage regulatory document collection process for multiple studies and assure consistency between studies
- Create and manage the clinical trial master file for multiple studies and assure consistency between studies
- Communicate daily with institution based clinical investigators/research staff (patient related safety, budget, data, monitoring staff, payments)
- Efficiently oversee multiple vendors for multiple studies (laboratories, contract research organizations etc.)
- Identify areas for process & technology improvement
- Responsible for meeting enrollment goals, budget goals and timeline goals for multiple studies
- Assist in protocol, informed consent and investigator brochure preparation
- Contribute to annual report, IND, clinical study report and grant application writing
- Contribute to other company related projects/departments as time allows
- Co-monitor as needed
- May have direct reports

Qualifications:

Education

- Bachelor's degree in a life science/Master's preferred or its equivalent in health care or biological science.

Experience/Skills

- Minimum of two years of clinical operations experience in the biotechnology or pharmaceutical industry as at a manager level
- Demonstrated understanding of all applicable regulations and guidelines governing drug development including ability to apply these to overall strategic drug development
- Excellent working knowledge of Good Clinical Practices; ICH guidelines; trial initiation and management practices and procedures
- Excellent leadership, interpersonal and communication skills. Works efficiently with others to accomplish goals and resolve problems. Encourages cooperation, collaboration, and co-ownership of processes
- Experienced self-motivated individual with a record of achievement as a result of past industry experience.
- Good conflict resolution and problem solving skills
- Strong interpersonal skills and matrix management skills
- Ability to develop a culture of teamwork, collaboration and communication.
- Excellent written and verbal skills and the ability to communicate clearly, concisely and effectively
- Open, available, transparent communicator with strong leadership, presentation and influence skills

Position Requirements:

- Ability to work on complex problems where analysis of situations or data requires an in-depth evaluation of various factors
- Available to travel for training, scientific meetings and co-monitoring or to assist with complex, difficult clinical sites
- Invest time to expedite and complete assignments or projects, as required
- High energy level, winning approach and the ability to advance group goals to meet company objectives

NOTE: This description is not intended to be all inclusive or a limitation of the duties of the position. It is intended to describe the general nature of the job which may include other duties as assumed or assigned.