Job Title: Clinical Operations Manager

**JOB DESCRIPTION:**
Independently manages multiple global clinical trials of moderate complexity. The CPM is expected to manage all sites and vendor (e.g. Clinical Research Organization) related issues, with supervision from the Director Clinical Operations. Simultaneously manages all aspects of multiple global clinical studies (Phase I through IV).

**ESSENTIAL DUTIES & RESPONSIBILITIES**

- Manages study operational plan and CRO activities, including project timelines & quality of deliverables, and managing approved trial budget(s) throughout the life of the assigned clinical trial(s)
- Participates in the selection of study vendors for assigned studies
- Maintains frequent and meaningful contact with CROs to assess performance and provide guidance as needed.
- Reviews and refines clinical operational plans including the study monitoring plan and other plans as needed
- Coordinates internal and external clinical development activities of all team members involved in the design and conduct of assigned clinical trials
- Contributes to relevant study documentation including clinical protocols, statistical analysis plan, clinical study reports as well as operational plans (CMP, DMP)
- Develop and manage study timelines (including recruitment) and may develop and manage program timelines
- Participates in the selection of investigational sites with input from Clinical/Medical Operations and vendors
- Assists with protocol design and medical issue resolution
- Proactively identifies project risks and resolves with some supervision
- Participates in study data review and other review activities as assigned
- Oversees clinical trial sites’ adherence to pertinent regulations through review of monitoring reports, CQA-GCP audit report, communications with investigators, study site personnel, CRAs, and other CRO/designee personnel
- Leads ongoing review of data to ensure GCP
- Oversees the submission of trial-related and essential documents to the Trial Master File
- Identifies and provides solutions to clinical trial issues and/or risks
- Represents Clinical Operations in cross-functional initiatives, as assigned by management, and may act on behalf of team when designated
- Provide or facilitate training to clinical study teams on assigned protocol specific topics
- Work closely with other teams in the organization, e.g. quality, regulatory, etc.
- Provide input into non-project related activities and development of department processes, procedures, and guidelines as requested
REQUIREMENTS

- BS or Master’s Degree in nursing, life science, or related field (or equivalent experience)
- Minimum of 8 years of clinical research experience, at least 3 of which are as a Project Manager for clinical studies at a CRO and/or pharmaceutical/biotech organization.
- Previous experience negotiating vendor/site contracts and managing the budgets
- Thorough understanding of FDA, ICH and GCP guidelines
- Experience with Phase I – IV clinical trials
- Proven track record showing clear proficiency in clinical project management skills
- Proven complex problem solving skills
- Solid vendor management skills, e.g. CRO, Laboratory & Clinical supply logistics
- Broad understanding of clinical operations related to clinical development functions
- Detailed understanding of all aspects of clinical protocol design and implementation & overall drug development
- Ability to effectively interface with medical personnel at clinical site(s)
- Ability to lead multi-disciplinary, cross-functional teams both internally & externally
- Ability to write and edit technical documents, such as protocols, protocol amendments, informed consent, and other trial-related documents
- Detail and team oriented with excellent cross-functional team leadership and participation skills
- Excellent interpersonal, verbal and written communication skills are essential in this collaborative work environment
- Proficiency with computer programs including Microsoft Office suite and Microsoft Project
- Ability and willingness to travel 25% of the time (internationally and domestically)

EOE

The above description is intended to describe the general nature of the job that may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.