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Associate Director/Director of Clinical Operations

REPORTING TO: Sr. Director, Global Clinical Research Operations

LOCATION: Corporate Office in Lexington, Massachusetts

RESPONSIBILITIES:

This role will be a key contributor to the company's clinical development and primarily responsible for the hands-on management and monitoring of early and late-stage clinical studies in ultra rare disease indications. This position reports to the Senior Director of Global Clinical Research Operations and will work closely with Program Management and Medical and Commercial Operations in the creation and management of the clinical development plans for rare disease programs and ultimately, driving the planning activities to ensure successful execution and completion of the clinical trial(s). The person should be an expert in the rare disease field that can drive timelines internally and externally.

- Leads the clinical trials implementation and has oversight of clinical trial CROs and clinical laboratory vendors.**
- Drives clinical sub-team meetings and collaborates with Clinical Research and Medical Operations to complete the following:**
 - Identification and management of Clinical Research Organization(s) and other contractors as needed.**
 - Conducts protocol feasibility analysis, country assessment, site identification, and patient recruitment planning.**
 - Identify investigators and provide assistance to facilitate timely selection of investigators and sites**
 - Recruitment of patients and manage logistics for getting patients to sites for clinical trials globally**
 - Site selection, conduct of site qualification visits and monitoring visits.**
 - Implement site selection, site monitoring and recruitment plans**

- Preparation and review of the protocol, CRFs, and informed consent forms.
- Prepare the coordinators manual, pharmacy manual, source documents, and other documentation required for the conduct of the global clinical trial(s)
- Collect and review essential documents for study start-up
- Ensure documents remain current during the course of the trial
- Maintain internal trial master file to ensure inspection readiness
- Interact with investigators to obtain necessary documentation and information before, during and after the study. Ensure accurate inventory of central, investigator site and core files on an ongoing basis to ensure that the files are complete and can be used as a source of reference.
- Ensure that the site personnel have a good understanding of the protocol and provide CRA training
- Maintain project tracking system on an ongoing basis to ensure that progress regarding the sites can be tracked.
- Assist with the preparation and presentation at investigator meetings as required to ensure that the clinical and investigational site staff team is well informed about the study and related procedures.
- Prepare and manage detailed project plan in MS Project and clinical study budget.
- Establish and ensure consistent use of clinical project planning processes.
- Interfaces with Program Management, Medical Operations and Commercial to develop integrated clinical and commercial plans.
- Represents Clinical Research in presentations to Senior Management
- Provides clinical input into the preparation of clinical portions of project INDs and other regulatory submissions.
- Create didactic presentations as needed to educate team members on disease background.
- Provide regular status updates of project progress to Head of Program Management and Chief Medical Officer.

REQUIREMENTS QUALIFICATIONS

- **Educated to degree level (biological science, pharmacy or other health related discipline preferred) or equivalent nursing qualification/experience.**
- **Minimum 7+ years of industry experience within clinical research/operations and 4 – 6 years study monitoring experience.**
- **Experience managing global clinical trials in rare diseases with orphan drug designation is a must.**
- **Demonstrated success in managing clinical study start-up for rare or ultra rare disease programs is a must.**
- **Proven track record of successfully delivering projects on time, to budget and the required quality.**
- **Excellent interpersonal, verbal and written communication skills (including experience in making presentations).**
- **Able to take initiative and work independently; sense of urgency in completing assigned tasks.**
- **Flexibility towards work assignments, new learning and travel (overnight, weekend and international travel may be required). Flexibility to accommodate travel up to 25-30%.**
- **Ability to manage multiple and varied tasks and prioritize workload with attention to detail.**
- **Team player with outstanding interpersonal, negotiation skills and organizational skills.**
- **Computer Proficiency: MS Office suite and working knowledge of MS Project required.**