Senior Manager, Clinical Operations

Position Code: 23062-18B2

Summary Description

Senior Manager, Clinical Operations is responsible for operational planning, implementation and conduct of assigned clinical trials outsourced to Clinical Research Organizations (CROs) and in compliance with applicable clinical and regulatory standards.

Key Responsibilities

- Manage the execution of phase 1-3 clinical trials in an out-sourced model from study start-up to final clinical study report; anticipate problems and propose risk mitigation plans to ensure successful and timely completion of the trials.
- Oversee CRO study conduct to monitor adherence to regulatory requirements, GCP per relevant contracts.
- Oversee CRO generation of applicable clinical documents, study-related manuals and procedures.
- Provide oversight of Trial Master Files for assigned clinical programs.
- Provide oversight and input to additional study-related external vendors, including execution of work and tracking of milestones and deliverables.
- Participate in Request for Proposals (RFP) and in the selection of CROs and other applicable vendors.
- Collaborate across a variety of functional groups including Clinical Development, Biostatistics and Data Management, Regulatory, Drug Supply, Project Management, Contracts and Finance to plan and execute responsibilities.
- Perform study site visits to provide Sponsor-level support as required.
- Provide clinical input to protocol and other documents as required.
- May assist with Standard Operating Procedure (SOP) development and implementation.
- This position has some project management responsibility and no direct reports, but will collaborate internally and with CROs to plan, execute and close out clinical trials.
- Some international travel will be required.

Experience & Education

- Minimum 6+ years of experience in trial management for industry sponsored trials, along with a Bachelor's of Science, Arts or other degree in a relevant scientific discipline is required. Experience as a clinical research monitor is an asset – knowledge and experience will determine level and title.
- Knowledge of FDA and/or EMA Regulations (or relevant local regulations), ICH Guidelines, and GCP governing the conduct of clinical studies
- Experience managing and working in eTMF systems is an asset
- Working knowledge and experience with Word, PowerPoint, SharePoint and Excel.
- Excellent interpersonal skills and demonstrated ability to lead is required
- Excellent verbal, written, interpersonal and presentation skills are required
- Creative problem solver with the ability to address issues quickly and independently, balanced with judgement to escalate issues as needed
- Strong attention to detail and dedication to accurate and high-quality work
- Focus on results, highly collaborative cross functionally, and proactive

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