Sr. Clinical Trial Manager/CTM

Position profile:

Highly autonomous and experienced clinical operations professional responsible for all aspects of Clinical Trials Management for a complex, global study from study start-up to close-out. Co-ordinates and leads Summit functional team members, CROs and vendors, to successfully deliver clinical studies under direction from Global Program Lead. Responsible for all performance metrics and quality of deliverables in the clinical trial.

Responsibilities:

- Oversees study scope, quality, timelines and budget with the internal Summit functional leads, CRO and vendors to ensure that overall project objectives are met.
- Initiates and builds solid professional relationships with key opinion leaders and clinical site staff.
- Partners with the CRO to ensure robust patient enrolment strategies are developed and carried out effectively to ensure patient enrolment is completed on time.
- Partners with the CRO to ensure robust ongoing data monitoring strategies are developed and carried out effectively to ensure delivery of high quality data.
- Proactive identification and management of study related risks.
- Responsible for the development and management of clinical trial documents including (but not limited to) protocols, Case Report Forms (CRFs), consent documents, confidentiality agreements.
- Responsible for reviewing and managing study related plans, processes including Investigator agreements (CTA), CRFs, CRF guidelines, statistical / pharmacokinetic analysis plans, monitoring plan, data management, safety monitoring
- Responsible for reviewing CRO and vendor contracts/work orders and specifications to enable study objectives to be met.
- Reviews and approves essential document packages to enable timely site activations.
- Reviews pre-study, study initiation, interim monitoring visit and at study closeout visit report. Provides close oversight on the findings on the monitoring reports and loops back with broader team to provide updates. Directs investigator performance and adherence to protocol, and proactively addresses conduct issues and enrollment problems, as necessary
- Responsible for oversight on the maintenance of the TMF and completeness at the end of the study. Perform periodic QC of the TMF
- Oversee the creation and execution of clinical trial activities in accordance with Good Clinical Practices. Ensure compliance of clinical trials with national and international regulatory requirements and co-monitoring the assigned clinical trial following company SOPs.
- Ensures the study is “inspection ready” always.
- Responsible for oversight and coaching of the functional activities of Clinical Trial Associates allocated to the project

Qualifications

- At minimum, bachelor degree or equivalent in life science, nursing, pharmacy, medical laboratory technology, or other health/medical related area preferred.
- A minimum of 7 years’ of clinical project management experience in conducting Ph I-III International clinical trials in Pharma/Biotech organization.

- A solid understanding of the drug development process, ICH guidelines/GCP and specifically, each step within the clinical trial process.
- Budget forecasting and management
- Experience with clinical studies in infectious or rare diseases would be a plus

Competencies & Skills:

- Demonstrated ability to lead teams and work in a fast-paced team environment.
- Experienced and enjoys building relationships with KOLs and site personnel. Willing to travel to establish relationships.
- Proven proficiency in overseeing large complex studies being managed by a CRO.
- Ability to successfully engage and work collaboratively with overseas clinical operations team members/colleagues.
- Demonstrated ability to build and deliver on patient enrolment strategies
- Excellent interpersonal and decision making skills. Demonstrates innovation, possesses drive, energy and enthusiasm to deliver the program objectives.
- Demonstrated ability to comprehend complex scientific concepts and data.
- Proficient in reviewing and assessing clinical data.
- Possesses excellent planning, time management & coordination skills.
- Demonstrated ability to problem solve and use clear judgment in relation to regulatory requirements, interactions with external parties, timelines, and complex clinical programs.
- Experience in working in a small organization
- Excellent written and oral communication skills.

Travel requirements: Must be able to travel internationally to visit clinical sites and for study meetings. Amount will vary upon project needs (20 to 40%).