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# Example of Clinical Study Manager Job Description

Our company is growing rapidly and is searching for experienced candidates for the position of clinical study manager. To join our growing team, please review the list of responsibilities and qualifications.

## Responsibilities for clinical study manager

* In collaboration with the Trial Monitoring key stakeholders (CSM Group Head, Regional Operations Manager (ROM), local/global medical, Trial Operations Manager (TOM), and global clinical assists in the development of local study execution plans and timeline commitments for a Country/Cluster
* Supports study feasibility and country patient commitments in collaboration with Country/Cluster Trial Monitoring and Medical
* Leads site selection in collaboration with Country/Cluster Trial Monitoring and Medical
* Ensures that study start-up activities are conducted and completed on time, including preparation of IRB/EC submission packages, review of Informed Consent Forms, engaging Regulatory Affairs/CTA Hub for Health Authorities submissions, as required, in collaboration with Country/Cluster Trial Monitoring stakeholders
* Ensures sites are prepared for “Ready to Initiate Site” (checkpoint), inclusive of written confirmation, and ensures all documentation is in place for initial and subsequent drug release in collaboration with the local Qualified Person(s)
* Is the escalation point for issues in monitoring visit reports (MVRs) for the assigned studies, post CRA Manager review (may act as primary reviewer in countries where CRA Managers do not exist)
* Provides feedback about the quality of monitoring activities to CRA Managers and local QA as appropriate
* Supports inspection readiness and submission preparation for monitoring related activities and assists with internal audits and HA inspections, as required, and ensures implementation of corrective actions within specified timelines
* Leads product development or marketing study programs in conjunction with and under direction of Clinical Affairs management, working closely with all departments and key stakeholders
* Manages clinical studies that involve sponsor-initiated studies OUS

## Qualifications for clinical study manager

* Able to work independently and manage assignments from a distance
* Strong understanding of cultural differences
* Proven client-facing relevant experience in healthcare, clinical research, project management or contract research organization
* Prior Project Management experience required, Critical Path Management preferable
* End to End study start-up experience & expertise preferred
* 3+ years experience in clinical research management