# Example of Clinical Study Manager Job Description



Our innovative and growing company is searching for experienced candidates for the position of clinical study manager. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

## Responsibilities for clinical study manager

- Establishes processes for the collection and initial review of regulatory packets and site contracts for investigator sites
- Oversees local vendor selection and performance as needed
- Drives the conduct of the study, (tracks status, maintains study level reporting systems, oversees forecasts, progress, and mitigation plans), to ensure all study operational aspects are on track
- Ensures recruitment targets are met and reviews enrolment at the site level including responsibility for approval of enrolling above site targets
- Oversees local clinical team activities to achieve study timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and local and international regulations
- Leads/chairs local study team meetings or supports Sr
- Maintains oversight of country level or assigned site level data management activities, including timely understanding of screen failure reasons and discontinuation rates, review of patient profiles, and proactively identifies data entry issues (on quality and timing) to mitigate queries, proactively identifies query resolution issues
- Coordinates the study handover process with the CRAs and their managers to ensure proper documentation and communication, when necessary
- Tracks that all study close–out activities are performed in a timely manner, in collaboration with CRAs and key study stakeholders
- Conducts or coordinates training, as needed, for CRAs to support site

standards, prevailing legislation, GCP, Ethical Committee and SOP requirements

## Qualifications for clinical study manager

- Proven ability to manage conflict and work under tight deadlines
- Be a member of the project team interfacing with R&D, Life Cycle Teams, Clinical Development Teams, Medical Affairs, Regulatory Affairs and Biometrics in the study overall design, validation and planning
- Bachelor's Degree in nursing, scientific, or equivalent required
- Scientific background in biological sciences
- Working knowledge of various tools used in clinical trials including electronic data capture, electronic clinical outcomes
- Bachelor degree or equivalent in life science, nursing, pharmacy, medical laboratory technology, or other health/medical related area preferred