

Position: Central Monitor

Department	Central Contracts & Proposal
Basic qualification required	B.Pharm / M. Pharm, M.Sc
Brief JDs	<p>Job Description :</p> <ul style="list-style-type: none"> • Manage assigned studies with minimal supervision. • Contribute to the development and use of Central Monitoring Plans and/or RBM specific tools and templates and/or other study specific plans. • Support project management team to develop monitoring strategy including monitoring triggers/thresholds. • With guidance, provide Inputs to clinical study teams, key decision makers, and internal team members to manage continuous process improvements, issue escalation, workload projections. • Perform centralized monitoring activities on assigned projects and evaluate the quality and integrity of the study as per the protocol, Sops respective regulation and guidelines. • Preparation of Site Performance Matrix (SPM) Tool for respective sites for assigned study (ies). • Participate in (study) team meetings/Project kick off meetings, client meetings and interaction with cross functional staff to verify information and/or triage new data issues. • Escalate quality issues pertaining to site and/or subject to respective stakeholder within the project team. • Perform Subject Level Data Review that require further investigation with the clinical site to determine overall accuracy (inclusion & exclusion criteria/ IP/AE/ Labs/EOT/EOS/ End points/SAEs etc.) • Perform the activities delegated and/or act as back up for/to relevant stakeholders within the project team • Conduct periodic review of KRIs, Trend Analysis points and share the output with Project Team. • Monitor site performance and make recommendations for timely corrective actions (e.g. Site Telephone Contact or Triggered Onsite Monitoring Visit) • Work in accordance of the Study Specific Central Monitoring Plan. • Establish and maintain effective project/ site level communications with relevant stakeholders. • Perform Source Data Verification (SDV) as per defined scope for the study. • To liaise with other departments within the organization for timely achievement of the project milestones.