

## Central Monitor

### PRINCIPAL DUTIES AND RESPONSIBILITIES:

- A. Manage assigned studies with minimal supervision.
- B. Contribute to the development and use of Central Monitoring Plans and/or RBM specific tools and templates and/or other study specific plans.
- C. Support project management team to develop monitoring strategy including monitoring triggers/thresholds.
- D. With guidance, provide Inputs to clinical study teams, key decision makers, and internal team members to manage continuous process improvements, issue escalation, workload projections.
- E. 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.
- F. Preparation of Site Performance Matrix (SPM) Tool for respective sites for assigned study (ies).
- G. 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.
- H. Escalate quality issues pertaining to site and/or subject to respective stakeholder within the project team.
- I. 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.)
- J. Perform the activities delegated and/or act as back up for/to relevant stakeholders within the project team
- K. Conduct periodic review of KRIs, Trend Analysis points and share the output with Project Team.
- L. Monitor site performance and make recommendations for timely corrective actions (e.g. Site Telephone Contact or Triggered Onsite Monitoring Visit)
- M. Work in accordance of the Study Specific Central Monitoring Plan.
- N. Establish and maintain effective project/ site level communications with relevant stakeholders.
- O. Perform Source Data Verification (SDV) as per defined scope for the study.
- P. To liaise with other departments within the organization for timely achievement of the project milestones.