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## Centralized Monitoring Lead

## #1716835

### PURPOSE

**Centralized Monitoring Lead (CML)** partners with the Clinical Lead and local country Site Monitors in project execution. Provides centralized support to monitoring visits and site management for a variety of protocols, sites and therapeutic areas. Monitors study start-up, manages resources, performs ongoing risk assessment through data trending and analytics and proposes potential mitigating actions in a timely fashion. Leads team of Clinical Monitor(CM) and Clinical Analyst Support (CAS).

### RESPONSIBILITIES

*Study Start-up*

- Maintains Clinical Operations Plan . Supports development of iSite Pack template, KDPMP and other tools/templates for DTE studies. Works with relevant stake holders for set-up and activation of DTE Alert/Triggers dashboard.
- Ensure the SSV Attributes and Monitoring Attributes are updated appropriately on QRPM. Request site monitor resources for site selection visits. Verifies training compliance and system access for the site management team involved during the study start-up.
- LCA or designee informs the monitor of all site activation critical elements that should be obtained to ensure the successful and efficient conduct of the site selection activity.
- Tracks site activation related critical elements on an ongoing basis before Site Initiation and keeps CL and Start-up Lead updated about the status of the site activation.

*Study Initiations*

- Requests monitor resource for site initiation and site monitoring. Verifies training compliance and system access for the site management team (CRA, CA and CAS) involved in the study site initiations.
- Coordinates with all stakeholders to start the site initiation activities once all site activation critical elements are obtained/resolved.

*Study Maintenance*

- Closely works with Site Monitor and CL during study execution phase with respect to recruitment and compliance to Clinical Operation Plan. Perform ongoing risk assessment through data trending and analytics and proposes potential mitigating actions in a timely fashion. Supports CRA in management of Quality issues.
- Manages DTE Alerts and other study specific triggers. Reviews status of action items and follow-ups with relevant team members for closure of action items. Escalates to Clinical Lead and PMA in case of significant delays in closure of action items if required.
- Sample review of iSite Pack (DTE studies), closed and open action items, Site Level documents on TMF.
- As applicable reviews Site Visit reports (for smaller studies with less than 20 reports per month)
- Review the RM Dashboard and resolve any items that need attention (i.e., Resource Assignment Errors, Queried Requests, and Inactive Resources Still Assigned).
- Manages resourcing and transition of study team members during execution phase. Provides training to Site Monitor, Clinical Analyst and Clinical Analyst Support if required.
- Reviews and approves Investigator Payments.
- Review and manages services requests received by CCO staff.
- Provides study updates to Clinical Leads as per study requirements.

*Study closeout*

- Reconciles action items, DTE alerts and study specific triggers.

## REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Advanced knowledge of clinical trial conduct, and skill in applying applicable clinical research regulatory requirements; i.e., ICH GCP and relevant local laws, regulations and guidelines, towards clinical trial conduct. Familiarity with related systems and software's utilized in clinical operations.
- Strong written and verbal communication skills including good command of English language
- Results and detail-oriented approach to work delivery and output
- Good problem solving skills
- Good planning, time management and prioritization skills
- Ability to handle conflicting priorities
- Attention to detail and accuracy in work
- Good software and computer skills, including MS Office applications including but not limited to Microsoft Word, Excel and PowerPoint
- Ability to establish and maintain effective working relationships with coworkers, managers and clients. Strong leadership skills
- Ability to work across cultures and geographies with a high awareness and understanding of cultural differences
- Act as a mentor for Clinical Process Associate colleagues

## MINIMUM REQUIRED EDUCATION AND EXPERIENCE

Bachelor's degree in life sciences or related field and min 2 years with relevant clinical research experience; or equivalent combination of education, training and experience