Site Exposure Program (SEP)
To bridge the knowledge & practical gaps between Data management, Central monitoring and Site personnel to gain insights on improved ways of working and implement innovative approach in process, tools and technologies.

- Reimagining our DM & RBQM role to adopt to ever changing landscapes of data trending and patient safety signalling.
- Skill enhancement for sustainable delivery with Site Management and Monitoring, Clinical data insights engagement.
- Scale up leadership capabilities through Exposure and Learning.
Overall Process

Planning Phase
- Two weeks prior to Remote Monitoring Visit
  - SEP Champion - DM
  - SEP Champion - SM&M
  - Nominate SEP Participants
  - Data Manager
  - Site Monitor

SEP Orientation and Participant Alignment
- One week prior to Remote Monitoring Visit
  - Orientation by SEP Champion - DM

Remote Monitoring
- Two weeks prior to Site Monitoring Visit
  - Site Monitor
  - Data Manager
  - Data management SEP participants prepare site interaction Q&A
  - Guide SEP participants about what to expect during Site monitoring Visit, Do’s and Don’ts

Site Monitoring
- Data Manager
- Site Monitor
- Site Staff

Debrief
- Data Manager
- SEP Champion -DM
- Engage
- Quarterly Meet
- SEP Champions Meet – DM and SM&M (SEP feed forward)
- SEP Champion share insights gathered during SEP engagement
- Technology enhancement forum
- DM Forum
- People | Role enhancement Forum
- Process enhancement forum
Business Benefits

### Company
- Reputation build by Data Management with Site staff.
- Skill enhancement of staff
- Art of story telling and listening
- Engagement of staff patient stories
- Integrated quality risk management plan
- Building site user experience on evolving and adoptive study designs and decentralized trials
- Embrace the patient centric data revolution

### People | Role
- Quality of engagement with site staff - Send issue precise queries to site (reduction in re queries, cancelled queries)
- People engagement through different types of site visits (SDV, SDR, RMV and MV)
- Better manage sample tracking and reconciliation by having insights on biological sample management at site
- Lean the validation process like ECO (edit check optimization)

### Process | Technology
- Unit cost reduction by understanding end user requirement
- Design eCRFs where information collection flow is similar in way data is entered in medical records [using CRF labels with close resemblance to medical source records]
- Elevate information presentation in existing dashboards and study metrics platforms
- Lean the validation process like ECO (edit check optimization)

### Apply Cross Functional Strengths
- CtQ (critical to Quality) data acquisition strategy
- Align data cleaning strategy with monitoring visit strategy to prevent end loading (eg: data entry, PI Signature)
- Functional efficiencies through impactful data insights
- Engagement through patient stories
- Reflection of site risk quality management strategy in eCRF and tSDV build
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