ABSTRACT

PROJECT DELIVERABLES:
This initiative was developed to:
• Enhance the delivery of accurate and reliable clinical trial data and results
• Verify the accuracy of submitted data
• Monitor protocol compliance in a timely manner
• Verify adherence to regulatory requirements for the protection of human subjects and handling of investigational agents
• Provide educational support to the PIs and study teams
• Enhance patient safety while participating in a clinical trial

BACKGROUND:
Per FDA Regulations and GCP Guidance, quality mechanisms, such as Monitoring and Auditing, are required for individuals who are the Sponsor of a Clinical Trial.

For continued assurance of meeting regulatory obligations, patient safety; and data integrity; MCCCC invested a substantial number of resources and funding to enhance and transform the quality activities, and to provide our investigators and clinical research staff with the highest level of quality, education, and support.

INTIAL STEPS:
• Benchmarked with external IIT monitoring and auditing programs
• Assessed for sustainability and viability
• Reviewed MCCCC IIT portfolio for impacted studies
• Requested MCCCC’s own IIT monitoring program
• Requested expansion of DSM quality activities (i.e., More frequent audits)

REVIEW AND ASSESSMENT:
• Defined and developed a Risk-Based Approach matrix to rate the frequency of auditing and monitoring based on risk level (moderate, high, elevated high)
• Collated benchmarked data to create an overall quality improvement initiative
• Grouped monitoring teams into two groups based on disease

DEVELOPMENT OF TOOLS AND SYSTEMS:
• Clinical Monitoring Plan
• Outcome report template
• Correspondence templates
• Developed REDCap systems that:
  • Correspondence templates
  • Audit and Monitor Visits
  • Outcome report template
  • Generates automated notifications of assignments
  • Tracks findings and trends

IMPLEMENTATION:
• Prioritization matrix
• Risk assessment and assignment of each study to an auditor and a monitor
• Technological challenges because auditors and monitors conduct visits remotely
• Process improvements and educational opportunities
• Monthly touchpoints between the auditing and monitoring teams

LESSONS LEARNED AND FUTURE DIRECTION:
• The tracking of monitoring and auditing reports is crucial to identify process improvements and educational opportunities.
• When building future reports, it will be imperative to include a member of the MCCCC Reporting and Analytics team in the build process to ensure all necessary elements of the reports can work and/or function appropriately within dashboards and trending reports.

REFERENCES
• REDCap 12.4.25 © 2023 Vanderbilt University

SOLUTIONS AND METHODS

IMPACT OF INITIATIVE

Figure 1 shows the risk-based frequency of auditing and monitoring

Figure 2 Highlights the synergist relationships across teams

Figure 3 is an example of the Prioritization Matrix used for Auditing and Monitoring trials.