Bold Forward Synergy: Auditors and Monitors Spearheading Transformative Change in Mayo Clinic Comprehensive Cancer Center Quality Initiatives

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ABSTRACT

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.

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
- Ensure patient safety while participating in a clinical trial

SOLUTIONS AND METHODS

Figure 1

Level of Risk	Risk Criteria	Audit Frequency	Monitoring Requirements	Quality Reviews	DSMB Review Frequency
Low Risk	Interventional non-treatment trials	For Cause	NONE	1st and 3rd Subject and Regulatory Review Regardless of Level of Risk	None, unless need determined by DSMC
Moderate Risk	Phase 2 and Phase 3Interventional treatment trials	Every 18 to 24 months from 1st subject accrued	• Within 12 weeks from 1st subject accrued • Every 12 months thereafter.		Every 6 months or more frequently as determined by DSMB
High Risk	Phase 1 and Phase 11/2 Interventional treatment trials	Every 12 to 18 months from 1st subject accrued	• Within 10 weeks from 1st subject accrued • Every 8 months there after		Every 3 months or until all subjects are off treatment.
Elevated High Risk	Early Phase, Pilot and Phase 1 Dose Finding Interventional treatment trials	Annually	• Within 8 weeks of subjects accrued • Every 4 months thereafter		Every 3 months or until all subjects are off treatment.

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

Figure 2

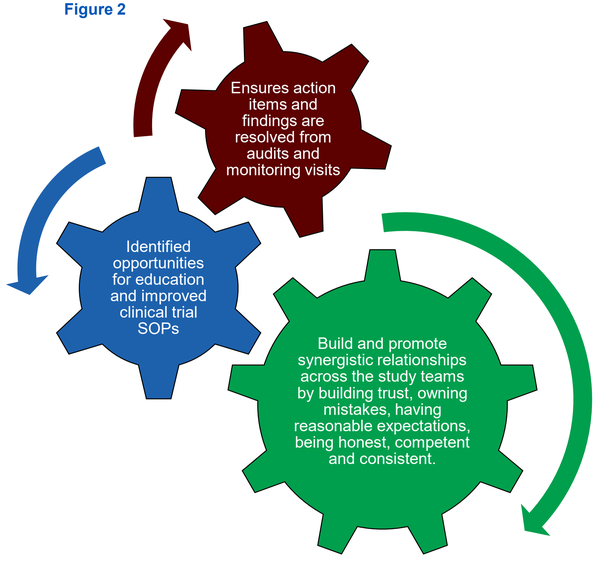

Figure 2 Highlights the synergist relationships across teams

INITIAL 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:
  - generates automated notifications of assignments
  - efficiently produces outcome reports of findings
  - 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
- Presented auditing and monitoring reports at Data Safety Monitoring Committee Meetings
- Monthly touchpoints between the auditing and monitoring teams

FIGURE 3

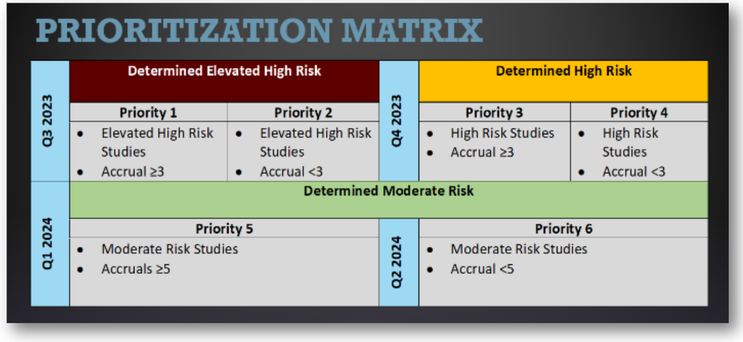

Figure 3 is an example of the Prioritization Matrix used for Auditing and Monitoring trials.

IMPACT OF INITIATIVE

Figure 4

	Pre-Implementation				Post-Implementation		
Timeline	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024
Audits Conducted	1	16	8	19	18	40	8
Monitoring Visits Conducted	0	2	6	8	37	48	63

Figure 4 provides data comparison of audits/visits completed pre and post new process

Figure 5

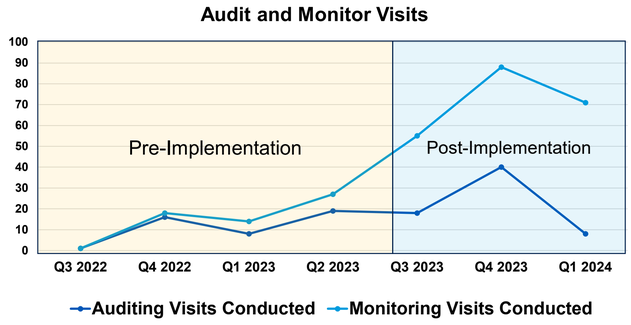

Figure 5 visually represents the visit comparison pre and post new process

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
- U.S. Food & Drug Administration (2018, March 22). *Title 21--Food and Drugs Chapter I, Food and Drug Administration Department of Health and Human Services Subchapter D-Drugs for Human Use Part 312.* U.S. Department of Health & Human Services. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=312