Category: Quality Assurance and Remote Monitoring and Auditing – Work in progress

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

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1. 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. Currently, the Mayo Clinic Comprehensive Cancer Center (MCCCC) manages over 160 Investigator-initiated Trials (IIT). 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.

2. Goals

To promote transformative change of the MCCCC Quality Initiatives, the goals for this project were to:

- Define criteria to determine the level of risk for each IIT
- Promote more real-time reviews of IITs
- Provide real-time education during study conduct
- Gain understanding of enterprise trends
- Develop a dashboard for our Compliance and Quality Board (CaQB) to utilize, which will assist with:
    - Identifying process improvements and/or gaps in processes
    - Lead operational change
    - Promote real-time oversight of study progress

3. Solutions and Methods

Quality initiatives were enhanced to properly realign MCCCC with ICH Good Clinical Practice (GCP), and the U.S. Food and Drug Administration (FDA) regulations. To achieve this, a comprehensive set of solutions and methods were developed and implemented to enhance the efficiency and effectiveness of monitoring and auditing processes within the MCCCC framework:

- Benchmarked with external IIT monitoring and auditing programs
- Defined and developed a Risk-Based Approach matrix to rate the frequency based on risk level (moderate, high, elevated high)
- Assessed for sustainability and viability
- Developed REDCap systems that:
    - Generates automated notifications of assignments
    - Efficiently produces outcome reports of findings
    - Tracks findings and trends
- Ensures action items and findings are resolved from audits and monitoring visits
- Improved opportunities to improve and modified clinical trial SOPs
- Identified methods for consistent education to study teams
- Build and promote synergistic relationships across the study teams

4. Outcomes

Implementation of the enhanced quality initiatives has led to:

- **Risk-Based Approach Implementation:** Greater oversight for trials deemed higher risk
- **Improved Operational Efficiency:** Integration of REDCap allowed for streamlined management, maintenance, and automation.
- **Quality Improvement:** Consistent education reinforced compliance with protocols and best practices
- **Collaborative Relationships:** Establishment of synergistic relationships across study teams promoted collaboration and reeducation

5. Lessons Learned and Future Directions

The tracking of our monitoring and auditing reports is crucial in the identification of 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.