Category: Training, Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Risk-Based Monitoring Model: Safeguarding Single-Center, Investigational New Drug, Investigator-Initiated Trials at Memorial Sloan Kettering Cancer Center

F. Puma, A. Granobles, K. Mantha-Thaler, K. Yataghene

Memorial Sloan Kettering Cancer Center

1. Background

Annual increases of investigator-initiated trials (IITs) and limited resources necessitated the adoption of a risk-based model (RBM) in 2017 by the clinical research quality assurance (CRQA) unit to ensure adequate sponsor oversight. In 2020, CRQA launched an innovative redesign of the RBM program focused on single-center, Memorial Sloan Kettering (MSK)-held investigative new drug (IND), IITs. The essence of the versatile RBM approach is defining and monitoring critical data points related to a protocol's primary and secondary objectives to mitigate risk and safeguard the safety, quality, and overall integrity of the clinical trial.

2. Goals

- Increase scope of monitoring oversight
- Standardize monitoring practices with creation of RBM tools and resources to ensure consistency of performance and improved oversight of staff
- Reduce source document verification
- Define key risk indicators based on protocol objectives

3. Solutions and Methods

RBM workflow process:

- Protocol selection
    - Utilize an institutional protocol risk assessment tool
    - Identify specific critical data points
    - Create an RBM plan with principal investigator approval
- Monitoring tools
    - Template presentation for monitoring initiation visit
    - Tracking and data collection toolkit for standardization of monitoring approach
    - Templates for monitoring visit reporting
    - Checklist for pharmacy visit and drug accountability
    - Robust and standardized index of deficiency categories
- Monitoring initiation
    - Present RBM plan
    - Review expectations of monitor and study staff during visits
    - Modify the RBM plan prior to finalization, if necessary
- Conduct routine monitoring visits
    - Verify participant data in source documents
    - Regulatory review
    - Pharmacy review, including drug accountability
    - Report generation

        - Summarize deficiencies and actions to correct and prevent their recurrence
        - Apply visit rating of "Acceptable," Acceptable - requires follow-up," or "Unacceptable," based on number of deficiencies identified

4. Outcomes

- Increased scope of monitoring
    - Increased by 100 percent the number of protocols reviewed in 2020 compared to 2019
    - Increased by 56 percent the number of monitoring visits conducted in 2020 compared to 2019
    - Increased by 21 percent the total number of participants monitored in 2020 compared to 2019
- Improvement in acceptable rating from 72 percent in 2019 to 86 percent in 2020

5. Lessons Learned

- Improved efficiency demonstrated by increased scope and productivity with fewer resources, less time and effort, and increased oversight
- Prevented non-compliance by identifying areas of risk and developing corrective actions with study teams
- Versatility of RBM approach allowed for the successfully adoption by multisite unit within MSK under the guidance of CRQA
- Future directions:
    - Continue improvement in efficiency through automation
    - Further redesign of the RBM program with application of lessons learned
    - Establishment of a monitoring council to ensure ongoing review of the monitoring portfolio to determine proper actions