Category: Quality Assurance & Remote Monitoring and Auditing - Work in progress

Developing A Central Monitoring Letter & Quality Audit Review

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1. Background

Conducting external monitoring visits (MVs) is crucial for ensuring adherence to protocols, maintaining data accuracy, and safeguarding the well-being of participants, particularly in complex oncology clinical trials in their early phases. Despite their vital role, confirming MVs and following up with letters present several obstacles for study teams and principal investigators, who must exercise oversight over the clinical trial's execution. Common issues include delays in addressing letters, limited review by immediate teams and PIs, and time constraints before the next MV, all of which pose challenges in identifying trends.

2. Goals

1. Enhance communication and responsiveness through our efforts
2. Standardize the filing naming convention and centralize collection for all team members to ensure efficient review towards resolution
3. Proactively address recurring issues by identifying patterns and trends at the study, investigator, and portfolio levels
4. Comply with Good Clinical Practice (GCP) guidelines and regulatory requirements to ensure timely and accurate regulatory reporting

3. Solutions and Methods

1. Centralized Email Address: We have established a dedicated email address for receiving MV follow-up letters
2. Smartsheet Implementation: By utilizing Smartsheet, we have developed a structured system for collecting, storing, and tracking the progress of MV follow-up letters
3. Weekly Monitoring Letter Review Committee: We have formed a multidisciplinary committee comprising representatives from various functional areas, including clinical operations, regulatory affairs, and quality assurance
    - This committee is responsible for reviewing and analyzing MV follow-up letters, prioritizing action items, and coordinating resolution efforts with PI oversight

4. Outcomes

Our weekly Monitoring Letter Review Committee examines all monitoring letters for upcoming visits, ensuring receipt and tracking of each letter. This allows us to review open items before the next visit, discussing with the monitor if needed. We take pride in systematically reviewing 100 percent of follow-up letters, tackling approximately 80 percent of open items with a resolution plan.

- Over 300 monitoring letters have been received since starting the project in mid-March 2023
- All monitoring letters were centrally reviewed during the week of the next monitoring visit
- Open items were addressed through a team approach with PI oversight
- Items that could not be closed through the team approach were addressed at the next monitoring visit

Additionally, we standardize all monitoring letters for easy access during audits, inspections, and internal monitoring.

5. Lessons Learned and Future Directions

Challenges arise when monitoring visits are not conducted frequently enough, leading to delays due to a lack of review in the weekly meeting before the next visit. Qualitative metrics can demonstrate improved external monitor relationships resulting from our site's timely response to monitoring letters, as well as our dedication to excellence in clinical trial conduct.

Our experience has emphasized the importance of proactive collaboration, process standardization, and the utilization of technology to streamline clinical research operations. Moving forward, we will refine our processes, optimize digital tools and platforms, and foster a culture of continuous improvement and innovation in oncology clinical research. We remain committed to staying informed about emerging trends and evolving regulatory requirements to advance the quality and integrity of clinical research practices in the pursuit of improved outcomes for oncology patients.