Developing A Central Monitoring Letter & Quality Audit Review

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Background:

Conducting external monitoring visits 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. These visits facilitate collaboration between external monitors and research sites, enabling timely and precise resolution of queries, identification of possible deviations, and provision of guidance for corrective measures. Despite their vital role, confirming monitoring visits 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 monitoring visit, all of which pose challenges in identifying trends.

Goals:

Our mission is to elevate the caliber of external monitoring relationships and streamline the follow-up procedures for monitoring and audit visit reports. Our objectives are as follows:

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.

Sample SmartSheet Snapshot

Visit Date	Protocol Number	Letter Received Date	MLC Review Date	R...	CRC	Regula... Coordi...	Data Coordi...	Status	Comple... Date	Notes
03/15/23	TACRI 2023-2024	03/30/23	04/03/23		TM Teri Mata	Melissa	Carmen	closed		
04/26/23	TACRI 2023-2024	05/09/23	05/15/23		TM Teri Mata	Melissa	Carmen	closed	07/11/23	signed
06/06/23	TACRI 2023-2024	06/13/23	07/24/23		TM Teri Mata	Melissa	Carmen	closed	07/11/23	signed
07/25/23	TACRI 2023-2024	08/18/23	09/11/23		TM Teri Mata	Melissa	Carmen	closed	08/18/23	signed

Solutions and Methods:

To effectively address the challenges and achieve our goals, we have implemented a comprehensive strategy consisting of the following components:

1. Centralized Email Address: We have established a dedicated email address for receiving monitoring visit follow-up letters. This ensures a streamlined and standardized process for letter submission, allowing for efficient handling and response.
2. Smartsheet Implementation: By utilizing Smartsheet, a versatile collaborative work management platform, we have developed a structured system for collecting, storing, and tracking the progress of monitoring visit follow-up letters. This platform allows for real-time visibility of the status of each letter by multiple team members, including the PI. It also facilitates efficient communication among stakeholders, ensuring seamless coordination and resolution of issues.
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 monitoring visit follow-up letters, prioritizing action items, and coordinating resolution efforts with PI oversight. By bringing together diverse perspectives and expertise, we ensure a comprehensive and effective approach to addressing any issues that may arise.

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% of follow-up letters, tackling approximately 80% 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.

Lessons Learned & 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.