

Getting Monitoring Deficiencies Resolved

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1. Background

Clinical site monitoring visits play a crucial role in ensuring that the rights and well-being of the study participants are protected, the quality and integrity of the data is maintained, and all study files and conduct of trial are in compliance with regulatory requirements. During these visits, monitors identify deficiencies or areas for improvement in the study design, data collection, and/or management processes. If deficiencies are not resolved in a timely manner, serious consequences may ensue, leading to inaccurate data, jeopardized participant safety, and compromised trial integrity. Therefore, timely resolution of monitoring visit deficiencies is essential to ensure the success and safety of clinical trials. At Memorial Sloan Kettering Cancer Center (MSK), the Clinical Research Quality Assurance (CRQA) monitors identified concerns that were putting the integrity and quality of the research at risk. The timeframe for deficiency resolution was continuously increasing for study teams, while time and effort for CRQA monitors was also growing. CRQA needed to develop a deficiency management process that would streamline deficiency resolution and increase overall efficiency.

2. Goals

Deficiency resolution took, on average, 60 days. The primary goals with developing a deficiency management process were to reduce deficiency resolution timelines and streamline the deficiency management by removing the need for monitors to re-review deficiencies without knowing if the study team had resolved them. The additional re-reviews were the cause of not having a way to confirm that study teams had taken actionable steps to resolve previously reported deficiencies. The re-reviews were repetitive, blinded, and time-consuming.

3. Solutions and Methods

The strategy was to develop the deficiency management system in the same platform where monitoring visit activities were entered; this would keep deficiency data centralized and ensure that appropriate standards and deadlines were met. The integration within the Protocol Information Management System (PIMS), an MSK-built system, allowed for real-time tracking, reporting capabilities, and a streamlined deficiency resolution process. At the conclusion of a monitoring visit, the deficiency management system sends automated emails every two weeks to the study team as long as deficiencies are listed as unresolved; this feature would maintain visibility and transparency.

4. Outcomes

After the implementation of the deficiency management process, deficiency resolution was brought down to an average of 26 days – a 57 percent reduction. The deficiency management process has improved monitoring proficiency, accountability, quality assurance management, and resolution timeliness, and reduced the need for corrective and preventive action plans.

5. Lessons Learned and Future Directions

A key component of the deficiency management system is its implementation within PIMS, which provides a centralized integration for data sourcing and the automation of communication for identifying and tracking deficiencies. The system's data were designed to be easily retrieved and reviewed by monitors and study team members assigned to resolve deficiencies; but additional

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stakeholders, including study team management and regulatory units, were interested in accessing the system for management oversight. The need for additional high-level access to the deficiency management system data led to the development of a dashboard that receives 76 views, with an average of 20 unique users, per month.