Getting Monitoring Deficiencies Resolved

Memorial Sloan Kettering Cancer Center

Adrian Granobles; Kamala Mantha-Thaler; Karima Yataghene, MD

BACKGROUND

Clinical site monitoring visits play a crucial role in ensuring that the rights and well-being of study participants are protected, the quality and integrity of the data is maintained, and all study files and conduct of trial are compliant 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 deficiencies is essential to ensure the success and safety of clinical trials. Memorial Sloan Kettering Cancer Center (MSK) was concerned with the increasing timeframe for deficiency resolution. Additionally, the dedicated follow up work by Clinical Research Quality Assurance (CRQA) Monitors on deficiencies was also growing as a result of the prolonged time to resolution. CRQA needed to develop a deficiency management process that would streamline deficiency resolution, increase overall efficiency, and ultimately maintain proper research integrity.

GOALS

In 2021, the average deficiency resolution time was sixty (60) days. The primary goals with developing a deficiency management process were to reduce deficiency resolution timeframe and streamline the management of deficiencies. One area of focus was to enable Monitors to identify unresolved and overdue deficiencies without additional time and effort. Improving the confirmation process of deficiency resolution would save Monitors from having to manually review, confirm the unresolved deficiency status, and re-issue them again. The confirmation process of deficiency resolution was repetitive, blinded, and time-consuming; a new process with more transparency needed to be implemented.

Reduce Timeframe

Streamline Process

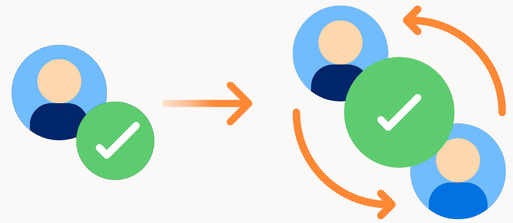
Improve Confirmation

METHODS

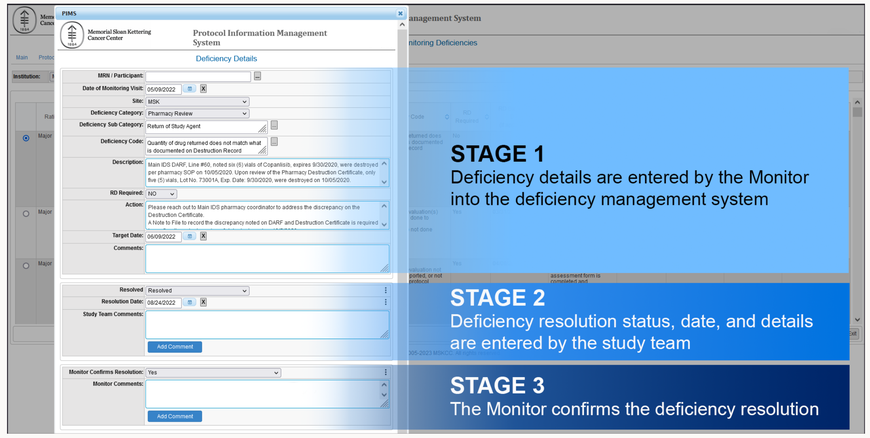
The strategy was to develop a deficiency management system using the platform already in place to support monitoring visit data. The use of this centralized platform would ensure consistent categorizations and leverage an existing powerful resource. At the conclusion of each monitoring visit, the deficiency management system sent automated emails to study teams informing them of deficiencies. Emails were sent every two weeks until resolution; this feature would maintain visibility, transparency for all stakeholders, and ensure accountability. Deficiencies would be considered resolved when deficiency resolution dates were entered by the study team and confirmed by the Monitor in the deficiency management system.

RESULTS

Deficiency resolution was brought down to an average of twenty-six (26) days, a fifty-seven percent (57% ↓) reduction.



The new deficiency resolution process change the engagement level of study teams from active participants to interactive participants.



CONCLUSION

The integration within the Protocol Information Management System (PIMS), an MSK-developed database system, allowed for real time tracking, reporting, and an overall streamlined deficiency resolution process. The deficiency management process improved monitoring proficiency, accountability, quality assurance management, and time to resolution.