

Strengthening Monitoring/Auditing Collaboration With Sponsors

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1. Background

The Monitoring and Auditing Tracking System (MATS) is a clinical research platform developed to track external monitor/auditor visitations. A primary function of MATS is to facilitate monitoring visits for Memorial Sloan Kettering's (MSK) industrial-sponsored portfolio with scheduling, requesting access to systems, collecting and sharing feedback, and storing relevant data. MATS enables real-time identification and communication of significant issues/trends immediately after an external monitoring/audit visit with the completion of its digital feedback form – the cornerstone of the MATS quality initiative.

The objectives of the feedback form are:

- Real-time communication of significant issues identified by external monitors/auditors to the principal investigator and research staff for immediate action
- Escalation pathway to clinical research leadership for awareness
- Evaluation of trends by the clinical research quality assurance unit across all departments/services as early risk indicators of patient safety, regulatory and/or protocol compliance data in 2019 indicated a decrease in feedback form completion

Due to the high value of the missing data, it was key to act swiftly to identify the reason for this non-compliance and implement process improvements to maintain and strengthen MSK relationships with its sponsors.

2. Goals

- Increase the completion rate by identifying the root cause(s) for non-compliance
- Improve the granularity of data received by revising feedback questions to improve utility when shared with stakeholders
- Maintain and strengthen relationships among MSK and sponsors

3. Solutions and Methods

- A cross-collaborative working group was formed within the clinical research administration (CRA) unit to dissect the process and content of the feedback form
 - Root causes identified:
 1. Awareness: increase messaging regarding compliance
 2. Education/instruction: simplify feedback form so that completion is more user friendly and intuitive
 3. Technical: monitors/auditors encounter technical issues while completing or submitting the feedback form
- Hands-on approach with its larger industrial partners (sponsors and CROs) to do the following:
 - Serve as consultants for the revamp of the feedback form content

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- Re-educate their staff on the importance of compliance
- Attend recurrent information session meetings with MSK to reinforce expectations for compliance
- Enhancements were made to the feedback form content, including improvement of significant data collected, and to streamlining the interface of the feedback form
- New document resources were developed to support all users

4. Outcomes

The implementation of the MATS enhancements resulted in:

- A consistent two-fold increase in feedback form compliance rate
- Positive trends in operational processes such as data entry and query resolution
- Observed reengagement by external monitor/auditor when technical or process questions arise

5. Lessons Learned

- Continue to explore additional ways to streamline and facilitate the completion process to further improve compliance
- Delineate data with more detail to unlock the full value potential of MATS
- Embrace opportunity to collaborate further both internally, across CRA, and externally, with sponsors, for information sharing and development of process improvements