



Strengthening Monitoring/Auditing Collaboration with Sponsors

Adrian Granobles; Francine Puma; Kamala Mantha-Thaler; Nicholas Cimaglia; Karima Yataghene, MD

BACKGROUND: The Monitoring and Auditing Tracking System (MATS) is a clinical research platform developed to better manage external monitor/auditor visits. A primary function of MATS is to facilitate monitoring visits for Memorial Sloan Kettering Cancer Center’s (MSK) industrial-sponsored portfolio with scheduling, requesting access to MSK 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.

FEEDBACK FORM OBJECTIVES:

- Real-time communication of significant issues identified by external monitors/auditors to the PI 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

PROBLEM:

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.

PROCESS:

- A cross-collaborative working group was formed to dissect the process and content of the Feedback Form
 - Root causes identified
- 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
 - Re-educate their staff with 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

IDENTIFIED ROOT CAUSES AND SOLUTIONS

Awareness

Increased messaging regarding compliance

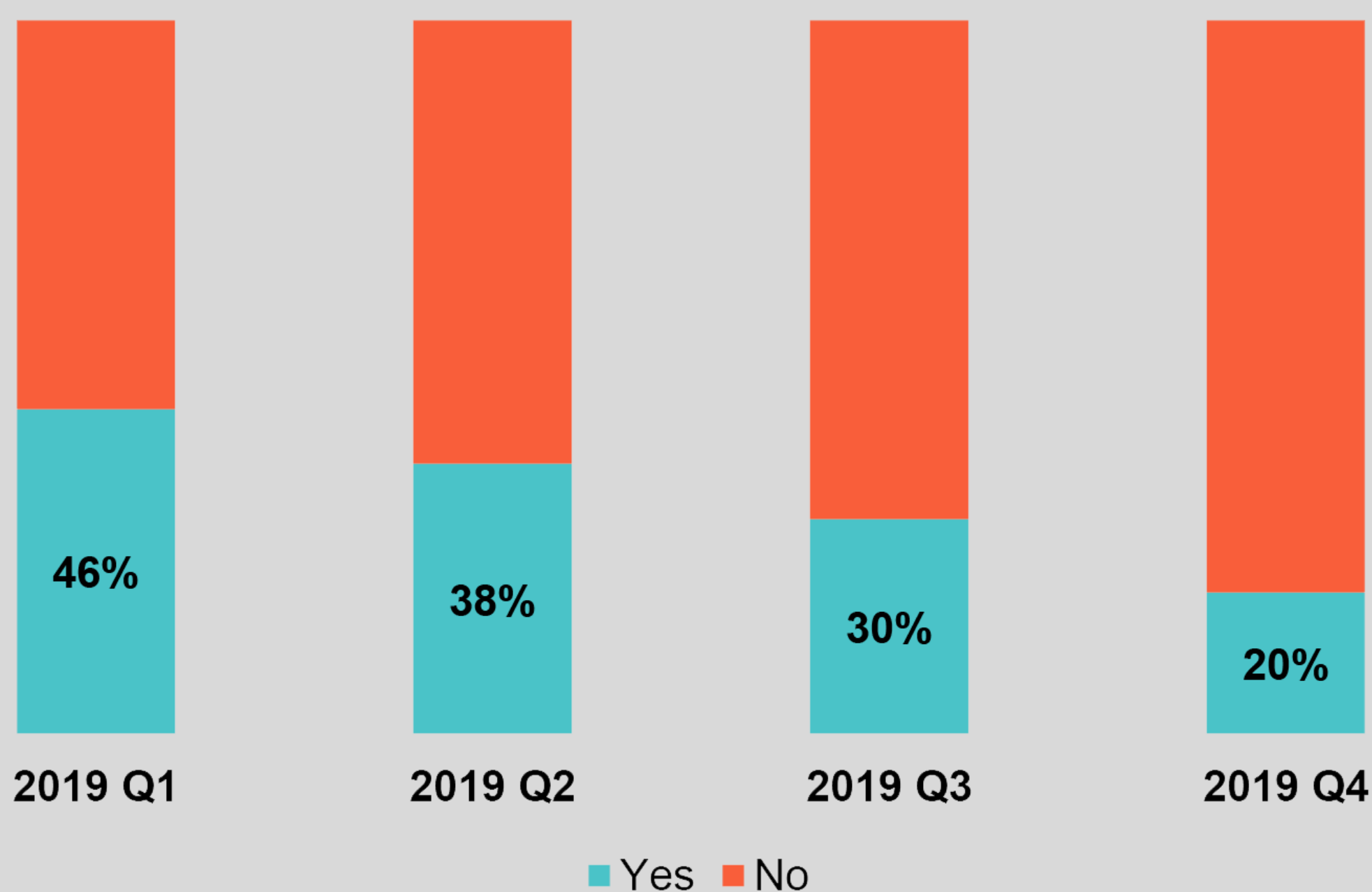
Education / Instruction

Simplified Feedback Form so that completion is more user friendly and/intuitive

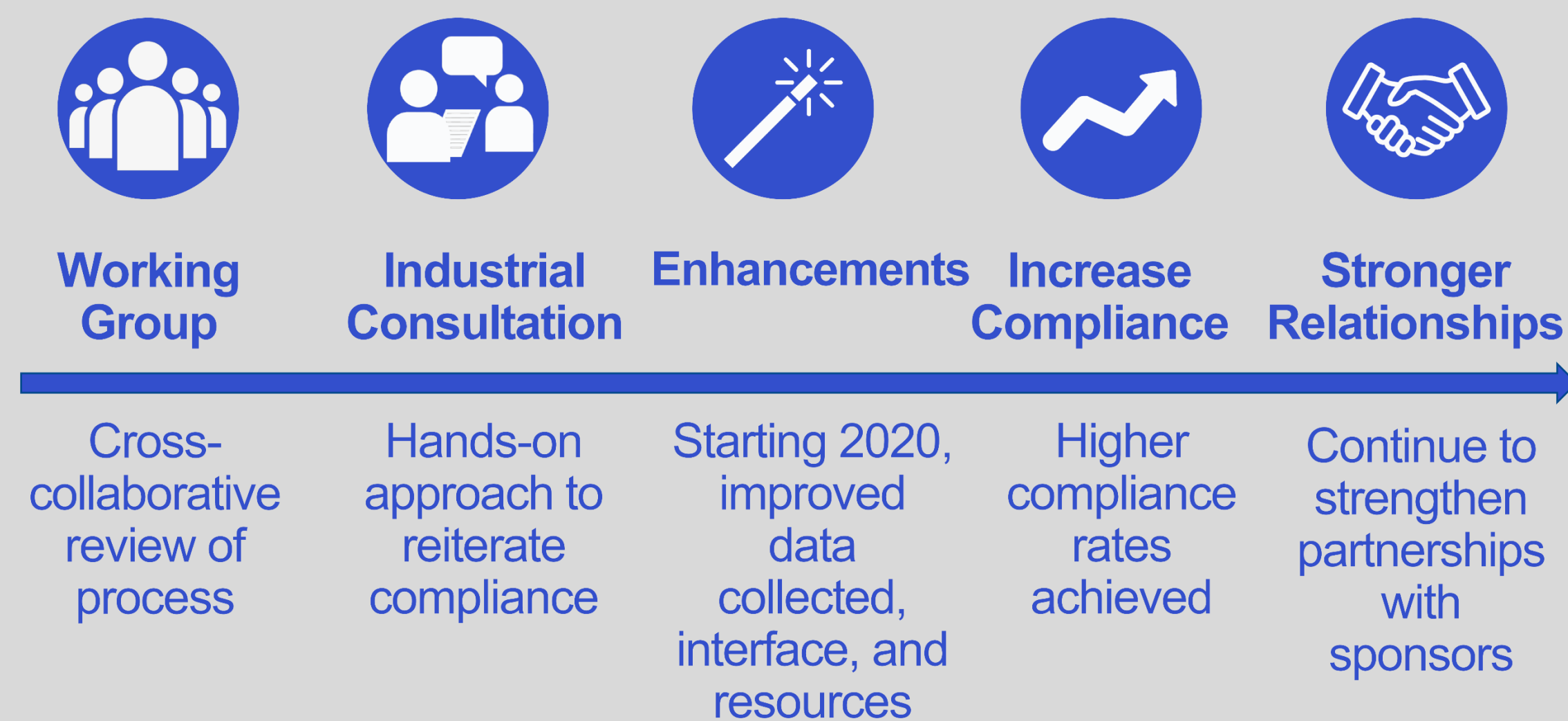
Technical

Monitors / Auditors encountered technical issues when submitting feedback; now there is consistent communication for resolutions

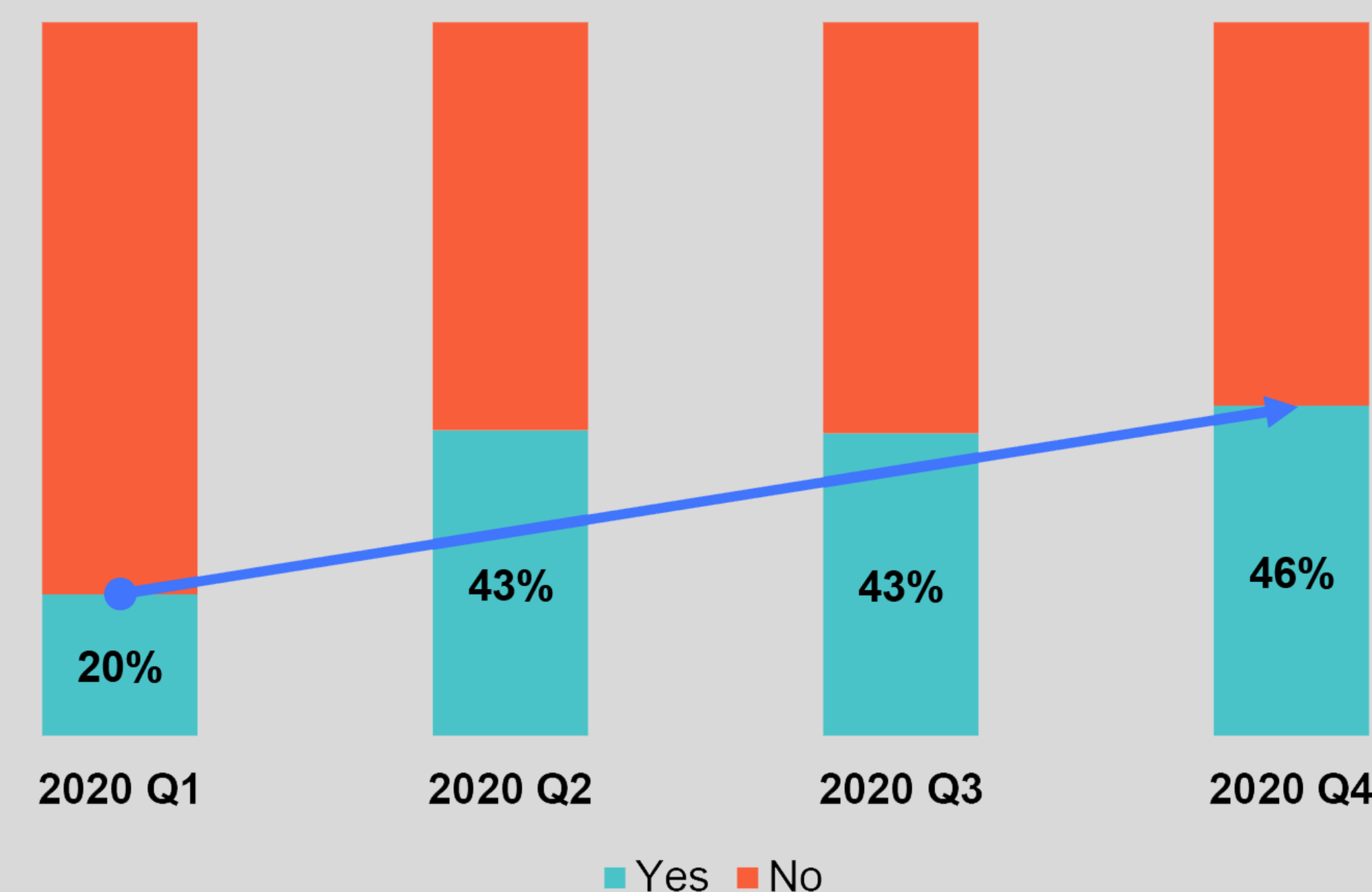
2019: Feedback Form Completed?



OUTLINE OF METHODS AND GOALS



2020: Feedback Form Completed?



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

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

CONCLUSION AND FUTURE DIRECTIONS:

- Continue to explore additional ways to streamline and facilitate the completion process to further improve compliance
- Delineate data more granularly to unlock full value potential of MATS
- Embrace opportunity to further collaborate internally and with sponsors for development of process improvements