Category: Training, Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Saved by Automation! How Technology and Innovative Thinking Significantly Increased Productivity of the MSK CR Audit Program

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1. Background

In 2017, the clinical research (CR) audit program at Memorial Sloan Kettering Cancer Center (MSK) was charged with increasing the scope of internal audits conducted across the clinical research portfolio. Prior to 2017, CR quality assurance conducted 22 audits of MSK clinical trials. This is in contrast to 2019 and 2020, where 99 (350 percent increase) and 125 (468 percent increase) risk-based audits, respectively, were conducted. Naturally, this resulted in a workload increase surrounding auditing activities, such as creating/finalizing audit reports, exposing the limitations of manual audit reporting.

2. Goals

As a result of the above, focus was turned to utilizing electronic systems, particularly the MSK Protocol Information Management System (PIMS) to increase productivity of audit report creation. PIMS is an in-house developed application that manages all steps involved with the protocol life cycle, including protocol auditing.

3. Solutions and Methods

The CR Audit Program conducts ~10 audits a month, each requiring a custom audit report to be completed, previously generated using Microsoft Word. In 2020, the CR Audit Program began working with PIMS IT developers to build a PIMS audit submissions module to automate the audit report process, which was successfully launched in June 2020. The PIMS audit submissions module allows the audit report to be built directly into PIMS and includes key features, such as automation and validation functionality, audit deficiency drop-down options and default deficiency ratings, a user-friendly interface and navigation, and a "My Queue" feature to track all pending audit assignments. Each member of the CR Audit Program was asked to estimate their time to completion (in minutes) for 10 audit reports (e.g., 5 reports pre-PIMS audit submissions and 5 reports post-PIMS audit submissions). The CR Audit Program managers, involved with reviewing audit reports, were also asked to average their time saved with their review process.

4. Outcomes

CR auditors are saving, on average, about 280 minutes (4 hours and 40 minutes) per audit. This is a 43 percent average increase in productivity. The CR Audit Program managers are saving, on average, about 240 minutes (4 hours) per audit, which is a 67 percent average increase in productivity. This process also eliminates manual entry of the audit deficiencies into the PIMS audit database.

5. Lessons Learned

The PIMS audit submissions module automation features have the greatest impact on the CR Audit Program's productivity. Most human errors are eliminated, and efforts are spent primarily on the quality of the deficiency content in the audit report.