Category: Quality Assurance & Remote Monitoring and Auditing - Completed Project

Saved by Automation! A Continuation of the Story of How Technology and Innovative Thinking Significantly Increased Productivity Surrounding CAPA Completion

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1. Background

In June 2020, the Clinical Research (CR) Audit Program, along with Clinical Research Informatics and Technology Unit and the Digital Products and Informatics Division, at Memorial Sloan Kettering Cancer Center, implemented the Protocol Information Management System (PIMS) audit submissions module to automate the audit report process. PIMS is an in-house developed application that manages all steps involved with the protocol life cycle. Details pertaining to this project were presented at the 2021 13th Annual AACI CRI Meeting.

From 2020-2022, an average of 116 audits were completed by the CR audit program with 97 percent requiring an internal corrective and preventive action (CAPA) plan to address audit deficiencies. A Microsoft Word CAPA template was used to capture CAPA responses. However, in preparation for completing a CAPA, a CAPA table had to be manually created for each unique audit deficiency, including manually entering each audit deficiency into the CAPA tables. A rigorous review and approval process was implemented to ensure audit deficiencies were appropriately entered into the CAPA template and to ensure effective CAPA completion and implementation. Naturally, this resulted in a workload increase exposing the limitations of manual CAPA completion in Microsoft Word.

2. Goals

As a result of the above and in continuation of the PIMS audit submissions module project, focus was turned to utilizing PIMS to increase productivity of CAPA creation, completion, and finalization.

3. Solutions and Methods

From late 2021 through October 2022, efforts were focused on incorporating a CAPA submissions component into the PIMS audit submissions module to automate the CAPA completion process, particularly to automate the input of audit deficiencies directly into a PIMS CAPA template. Other key features include automation and validation functionality, root cause drop-down options, recommended corrective/preventive action plan drop-down options based on the chosen root cause, a user-friendly interface and navigation, and a “My Queue” feature to track all pending CAPA assignments. Research staff completed a survey to estimate their time to completion (in minutes) for CAPAs worked on, pre-PIMS and post-PIMS (i.e., estimated time to: 1) create the tables in the Microsoft Word template, pre-PIMS; 2) complete the CAPA responses, pre-PIMS and post-PIMS; 3) review the CAPA prior to submission, pre-PIMS and post-PIMS; and 4) make updates and finalize the CAPA after receiving comments/corrections from the CR Audit Program, pre-PIMS and post-PIMS).

4. Outcomes

An average of 468 minutes is being saved per CAPA, resulting in a 41 percent increase in productivity. Specifically, 91 minutes are saved by avoiding manual entry of audit deficiencies into the CAPA template. Research staff is also saving 113 minutes, 29 minutes, and 236 minutes, respectively, on completing CAPA responses, on CAPA reviews prior to submission, and on updates after receiving comments/corrections from the CR audit program.

5. Lessons Learned and Future Directions

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The automation of CAPA submissions has demonstratively increased the productivity of the CAPA completion process, resulting in efforts spent primarily on the quality of the CAPAs. Invaluable feedback has also been collected and will be taken into consideration for future modifications and enhancements to the PIMS CAPA submissions process.