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

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BACKGROUND

In June 2020, the Clinical Research (CR) Audit Program, along with Clinical Research Informatics and Technology (CRIT) Unit and the Digital Products and Informatics (DigITs) Division, at MSK, 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, 116 audits, on average, were completed by the CR Audit Program with 97% requiring an internal corrective and preventive action (CAPA) plan to address audit deficiencies. A Microsoft Word 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 captured in 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.

GOALS

In continuation of the PIMS Audit Submissions Module project, from late 2021 through October 2022, focus was turned to utilizing PIMS to increase productivity of CAPA creation, completion, and finalization.

METHODS

The PIMS CAPA Submissions Module was successfully launched in October 2022.

This Module allows CAPAs to be built directly into PIMS and includes key features:

- Automation and validation functionality
- Direct entry of CAPA responses into a database
- Root cause drop-down options with recommended Corrective/Preventive Action Plan drop-down responses based on the chosen root cause
- User friendly interface and navigation
- “My Queue” feature to track all pending CAPA assignments

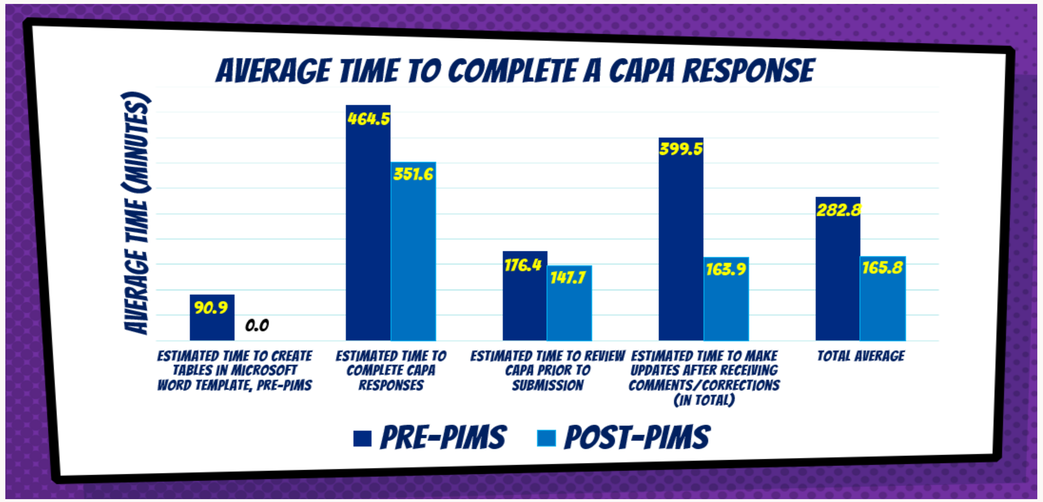
To understand time-saved and improved efficiency, research staff completed a survey to estimate their time to completion (in minutes) for CAPAs worked on, pre-PIMS and post-PIMS Submissions Module implementation.

CAPA Reporting Process Includes (measured in time)

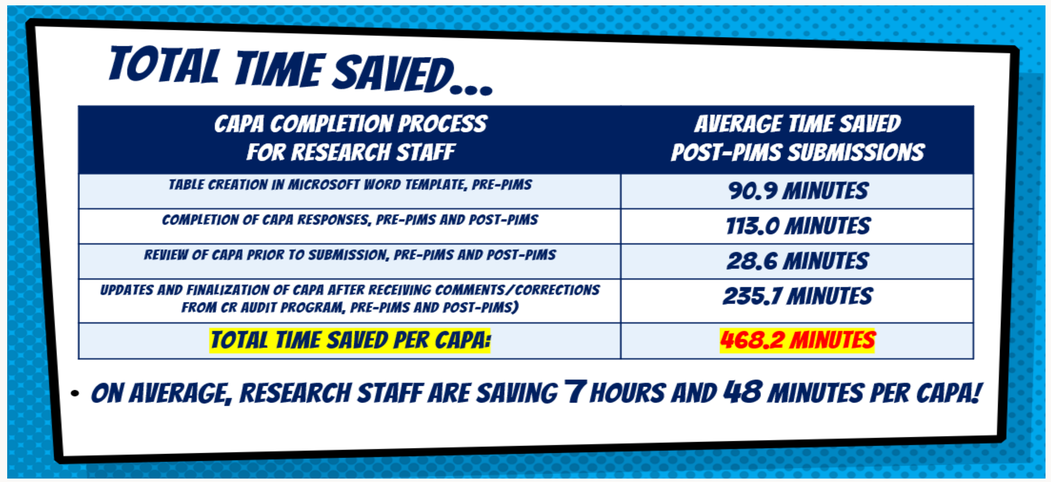
1. Table creation in Microsoft Word Template, pre-PIMS
2. Completion of CAPA responses, pre- and post-PIMS
3. Review of CAPA prior to submission, pre- and post-PIMS
4. Updates and finalization of CAPA after receiving comments/corrections from CR Audit Program, pre- and post-PIMS)

RESULTS

Twenty-three (23) research staff responded from various MSK departments/services. Estimated time to complete CAPA responses, pre-PIMS (avg 8.5 CAPAs completed) vs. Post-PIMS (avg 3 CAPAs completed), was calculated.



How Much Time Does it Save and How Successful Is It?



RESEARCH STAFF→ 41.4% AVERAGE INCREASE IN PRODUCTIVITY

CONCLUSION

1. PIMS CAPA Submissions Module has demonstrably increased productivity and efficiency of the CAPA completion process, resulting in efforts spent primarily on the quality of CAPA responses.
2. Most “human” errors have been eliminated as a direct result of PIMS automation.
3. CR Audit Program now handles a significant workload increase while reducing errors and omissions and improving quality.
4. Invaluable feedback has also been collected and will be taken into consideration for future modifications and enhancements to the PIMS CAPA Submissions process.

Most Common PRO: “It is organized and easy to follow. It allows the team to focus directly on resolving the issues/findings rather than building the template/form as we did in the past.”

Most Common CON: “[PIMS CAPA Forms] cannot be edited by multiple parties at the same time.”

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