



Saved by Automation! How Technology and Innovative Thinking Significantly Increased Productivity of the Clinical Research (CR) Audit Program

Jacqueline Simpronio & Susan Puleio, ACRP-CP, CCRP

BACKGROUND

In 2017, the 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. Previously, in 2016, CR Quality Assurance conducted 22 audits of MSK clinical trials. This is in contrast to 2019 and 2020, where 99 (350% increase) and 125 (468% increase) risk-based audits, respectively, were conducted. Naturally, this resulted in a workload increase surrounding auditing activities [e.g., creating/finalizing audit reports], thus exposing the limitations of manual audit reporting.

The CR Audit Program conducts ~10 audits a month, each requiring a custom audit report to be completed, previously generated using Microsoft Word.

Focus was turned to utilizing electronic systems, particularly the MSK Protocol Information Management System (PIMS), in order 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.

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.

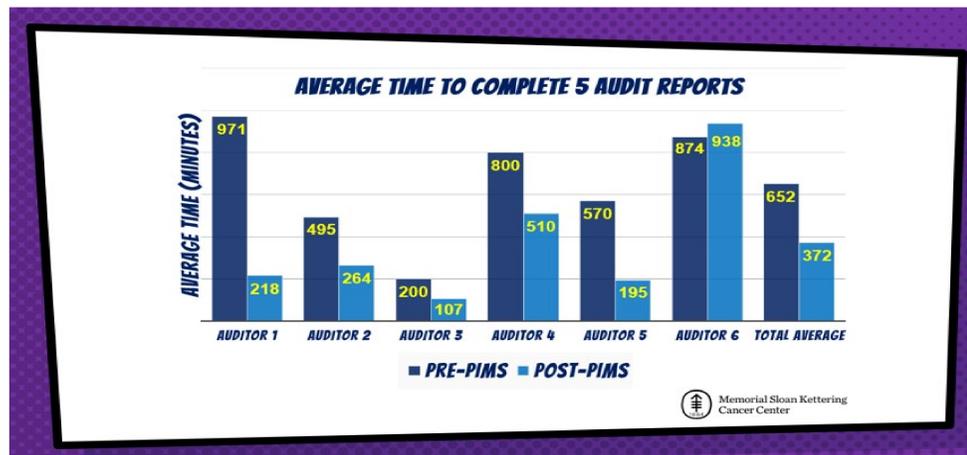
METHODS

The PIMS Audit Submissions Module was successfully launched in June 2020.

This Module allows the audit report to be built directly into PIMS and includes some of the following key features:

- Automation and validation functionality
- Direct filing of audit reports into an audit database
- Audit deficiency drop-down options and default deficiency ratings
- User friendly interface and navigation
- “My Queue” feature to track all pending audit assignments

RESULTS



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

To fully understand time-saved and improved efficiency, data collected was calculated on each level of the Audit Reporting Process, pre- and post-PIMS Audit Submissions Module implementation.

Audit Reporting Process Includes (measured in time)

1. Data Entry into Word Document vs PIMS Audit Submissions Module
2. First Level Manager Review of Report, Pre-PIMS vs. Post-PIMS
3. Second Level Manager Review of Report, Pre-PIMS vs. Post-PIMS
4. Final Auditor Corrections of Report, Pre-PIMS vs. Post-PIMS
5. Manual Copying of Data from Word Document into Audit Database Prior to PIMS Audit Submissions Module Implementation

Six Auditors estimated time to complete 5 initial audit report, pre-PIMS vs. Post-PIMS.

Estimates were calculated using the following criteria:

1. Estimated time to enter audit deficiencies
2. Estimated time to tally deficiencies and extrapolate summary sections
3. Estimated time to review completed audit report prior to first level manager review
4. Estimated time to make updates after receiving comments/corrections (in total)

Additionally, two Audit Team Leads and CR Audits Manager averaged their review time, pre-PIMS vs. post-PIMS.

TOTAL TIME SAVED...

CR Audit Personnel Involved in Audit Report Process	Total Time Saved (in minutes) Post-PIMS Submissions
CR Auditor	279.79 (4 hours and 40 minutes)
Team Lead	180
Audits Manager	60
Data Specialist	45
Total Time Saved Per Audit:	564.79 (9 hours and 20 minutes)

- ON AVERAGE, AUDIT MANAGERS ARE SAVING ~ 240 MINUTES PER AUDIT!
- ON AVERAGE, CR AUDITORS ARE SAVING ~ 280 MINUTES PER AUDIT!

CR AUDITORS → 43% AVERAGE INCREASE IN PRODUCTIVITY

CR AUDIT MANAGERS → 67% AVERAGE INCREASE IN PRODUCTIVITY

CONCLUSION

1. PIMS Audit Submissions Module has demonstrably helped the CR Audit Program function more efficiently.
2. Most “human” errors have been eliminated as a direct result of PIMS automation.
3. CR Audit Program now handles significant workload increase while reducing errors and omissions and improving quality.
4. CR Audit Specialist, previously responsible for manually entering audits into audit database, spends more time working on metrics and special projects and less time on data entry.

ACKNOWLEDGMENTS

MSK CR Informatics and Technology (CRIT) Unit

PIMS IT Developers
• Michael Ayerov
• Haritha Daggumati

CR Audit Program

- Karima Yataghene
- Nara Chhua
- Debbie Marcellus-Duval
- Danae De Blasi
- Reena Dholakia
- Charina Duarte
- James Lozada
- Michael McGinn
- Ashley Soh
- Jennifer Tom
- Vimal Singh
- Jane Myers
- Jean Kelly