

Implementing a Risk-Based Approach to Corrective and Preventive Action (CAPA) Management

Kristen Connal, Katrina Croghan, Jessie Powell, Keith Severson, Lisa Winkowski, Amanda J Youssef M.S, Jade Zbacnik, Angela Fritsche, Grzegorz Nowakowski, M.D., Pooja Advani, M.D., and Aaron Mansfield, M.D.
Comprehensive Cancer Center, Mayo Clinic

BACKGROUND

In 2021, Mayo Clinic Comprehensive Cancer Center (MCCCC) implemented a new Corrective and Preventive Action (CAPA) management system that focused on a streamlined approach to assist with implementation of CAPAs and CAPA effectiveness checks.

Despite the benefits of this approach, there were still components that did not meet the requirements of a true Quality Management System (QMS). Additionally, this approach placed an operational burden on the MCCCC Compliance and Quality Unit (CQU). In 2023, the CQU and QMS re-evaluated the CAPA management process.

CAPA Management is available for all Cancer- Related trials and institutional partners and tracked through REDCap. Finalized CAPAs are provided to the Compliance and Quality Board for review and determination.

GOALS

To ensure that MCCCC CAPAs maintained the highest quality, met QMS standards, remained objective and provided real-time automation, the CAPA process was enhanced to:

- Enable front-line staff to input all the necessary information into the CAPA system to facilitate:
 - Natural flow of information,
 - Eliminating back-and-forth between study team/departments and CQU
- Create a risk-based algorithm to determine whether a CAPA plan is required
- Eliminate subjectivity caused by the variability of the CQU Reviewer
- Update the REDCap system to:
 - Include risk-based algorithm
 - Automated communication alerts (i.e., CAPA determination)
 - Provide trend reports
- Reduce timelines

SOLUTIONS AND METHODS

CAPA PLAN TRACKING IN REDCap

- Provide objective risk assessments to determine if CAPA plans are required
- Ensure CAPA Plan timelines are met
- Monitor larger trends/opportunities for operational growth
- Provide one repository for all Cancer-Related CAPA plans
- Allow Compliance and Quality Board (CaQB) access

CAPA NOTIFICATION EFORM

A CAPA request eForm is completed when Cancer-Related staff become aware of procedural gaps and/or study-specific trends. The eForm is programmed to conduct a real-time risk assessment by asking specific questions that calculate values based on requestors response (Figure 2). The calculated risk level will determine if a CAPA Plan is required.

Once the eForm is completed, the requestor will be able to view the determined level of risk within the eForm, as well as receiving an automated email notification with the risk level determination.

Throughout the CAPA Plan lifecycle, notifications have been built into the REDCap tool which allows real-time communication to the requestor of the CAPA plan completion status.

Figure 2

Table 1: Probability of Occurrence of Harm			Table 2: Severity of Harm		
Value	Definition	Qualitative	Value	Definition	Qualitative
20	Frequent	Likely to happen often	15	Critical	Affects critical functionality, data, serious patient injury, or death
16	Probable	Likely to happen	11	Major	Affects major functionality, data, or injury requiring medical intervention
12	Occasional	Can happen	7	Minor	Affects insignificant functionality, data, or operational processes, or a more serious level of harm that can be reduced to this level or lower through a workaround that exists or can easily be built
8	Remote	Unlikely to happen	3	Negligible	Inconvenience
4	Improbable	Negligible likelihood of occurrence			

Definitions for Occurrence and Severity of Harm which is used to determine Risk Level (see Figure 3)

CAPA MANAGEMENT TOOL SET-UP

A 5x5 risk matrix, developed by the Department of Defense (DOD), was adopted and incorporated into the CAPA Management REDCap tool (Figure 1). The matrix:

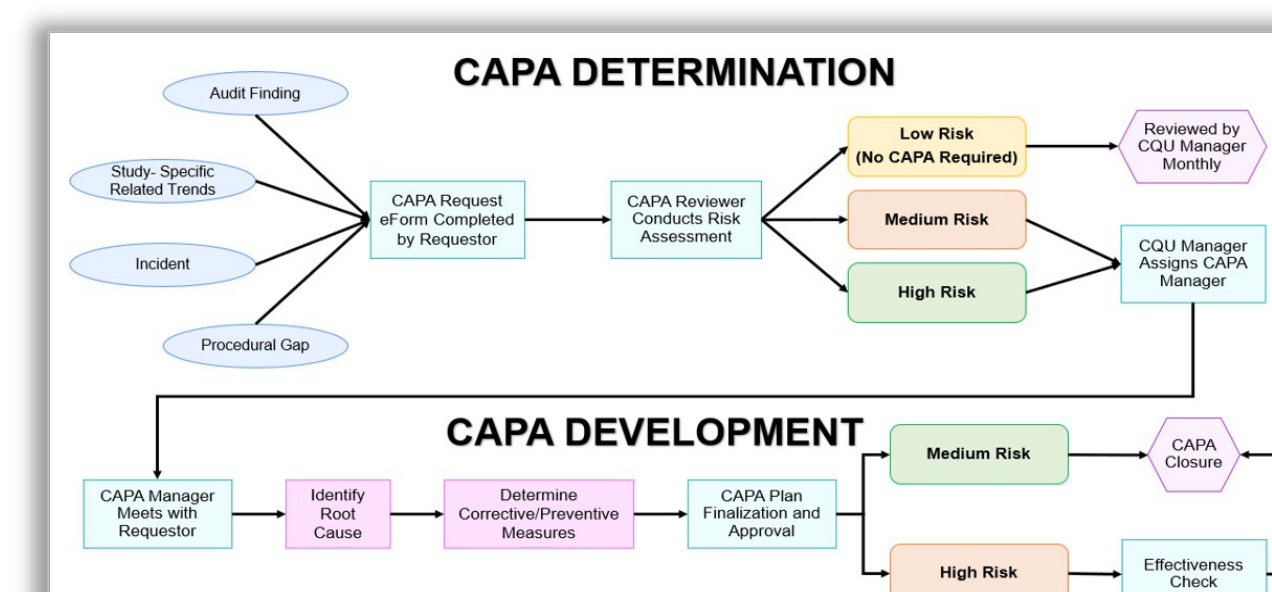
- Empowers requestors to identify if the potential CAPA requires a submission to the CQU.
- Quantifies the frequency of occurrence and the severity of harm.

Figure 1

Probability of Occurrence of Harm	Severity of Harm			
	Negligible	Minor	Major	Critical
Frequent	Medium	Medium	High	High
Probable	Low	Medium	Medium	High
Occasional	Low	Low	Medium	Medium
Remote	Low	Low	Low	Medium
Improbable	Low	Low	Low	Medium

5x5 risk matrix based of Occurrence and severity harm scores

Figure 3



CAPA determination and subsequent plan development

CQU CAPA MANAGEMENT PROCEDURE

MCCCC CQU Team receives all CAPA requests and determinations to ensure effective oversight of CAPA management process (Figure 3). Within 48 hours, Medium or High Risk CAPAs are reviewed and assigned a CAPA Manager who will manage a CAPA Plan from initiation to finalization. The Low Risk CAPAs are reviewed by the CQU Manager monthly.

During the development of the CAPA Plan, CAPA Manager will meet with the requestor and any impacted parties to identify root cause(s) and to determine corrective and preventive measures.

CAPA Managers will collate all information into a REDCap CAPA Plan and route for finalization and approval.

OUTCOMES

The implementation of the new CAPA Management process has vastly improved:

- CQU CAPA reviewers' confidence that CAPA requests meet the MCCCC CAPA plan requirements
- CAPA reviewers' effort as it allowed the requestors (i.e., study teams/department) to provide more information upfront,
- Human error and subjectivity from the CAPA reviewers.

The new process has also:

- Increased study teams' awareness
- Provided instantaneous determination and notification
- Promoted tracking of all CAPA requests
- Enabled reviews to determine trends and systematic glitches
- Standardized CAPA timelines
- Decreased hands-on time

LESSONS LEARNED

- We need to be able to identify process improvements and educational opportunities. We are developing a Satisfaction Survey for CAPA teams. This will allow CQU to obtain feedback.
- The REDCap system provides a PDF export documenting the entire review process and associated outcomes. This will allow for consistent messaging between study teams and sponsor inquiries.
- CQU plans to build dashboards to visually identify trends.

REFERENCES

1. REDCap 12.4.25 - © 2023 Vanderbilt University
2. Department of Defense (2017) *Risk, Issue, and Opportunity Management Guide for Defense Acquisition Programs* (pp 27-30). Department of Defense.