Protocol Categorization System to Improve Activation Timelines of Mission Critical Research

Memorial Sloan Kettering Cancer Center

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Background

- Memorial Sloan Kettering Cancer Center (MSK) activates over 300 prospective protocols each year. Improvements to the time it takes to activate protocols has always been our priority.
- In the past few years, increased volume and complexity of protocols coupled with the pandemic in 2020 and “The Great Resignation” of staff throughout the institution placed an additional strain on our system. It became apparent that our volume surpassed resources, resulting in ineffective management of our activation goal for all protocols.

Goals

Given our finite resources and expanding portfolio, a protocol categorization system was proposed by leadership to focus our efforts for quick activation on a more manageable volume of protocols critical to MSK’s mission.

The goal was to categorize protocols as:

- **Mission Critical (MC):** protocols critical to our mission, for which our goal was to activate in a reduced amount of time
- **Priority:** All priority protocols were expected to activate according to our standard institutional goal for activation.
  - **Time Sensitive:** began activation at the time of submission
  - **Not Time Sensitive:** began activation when institutional resources were available.

Methods

- To operationalize this categorization system, leadership determined the monthly number of protocols permitted to begin activation, based on the monthly number of protocols successfully opened to accrual using our current resources.
- Each service (disease group) was given an allocation of slots for MC. MC protocols were prioritized by all teams (i.e., finance, legal, research operations, study start up, protocol review, etc.) (Figure 1)
- Detailed communication plans were developed between groups, starting when a protocol was accepted for activation.
- Bi-weekly meetings were established with stakeholders of study start up to escalate potential barriers to activation early in the process.
- Our team created workflows and dashboards to track protocol allocations by disease group and time to activation timelines.

Figure 1: Protocol Allocations by Disease Group

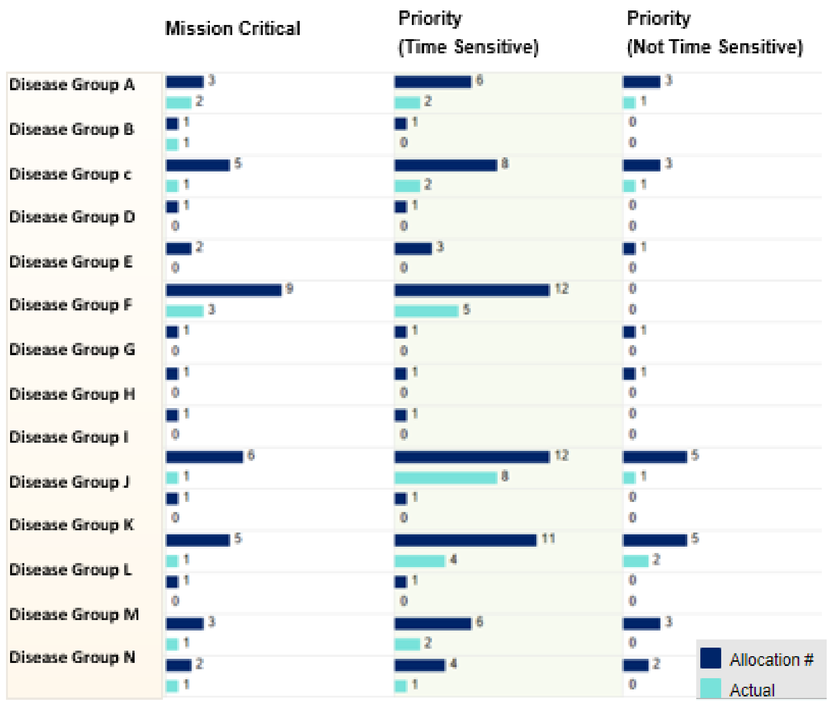
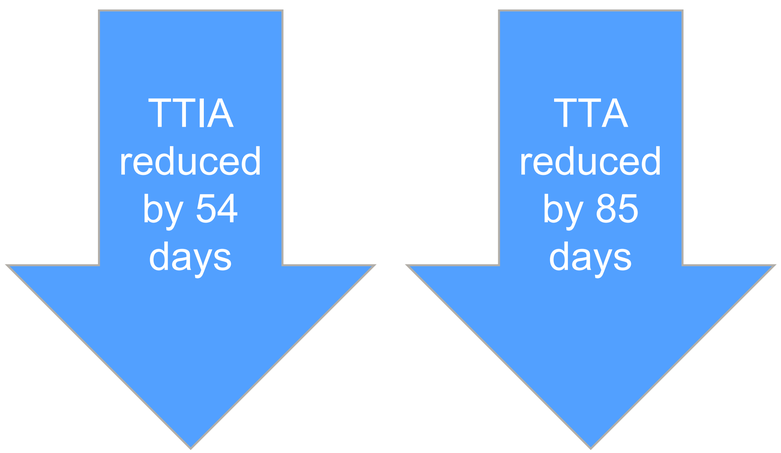


Figure 2: TTIA & TTA Reduction in Mission Critical protocols when compared to Priority protocols



Outcomes

- Since the roll out of the categorization system (as of 5/11/2023), **246** protocols were **IRB approved**, **180** of which have been **activated**.

	# of Categorized Protocols Accepted for Activation	# of IRB Approved Categorized Protocols	# of Open to Accrual Categorized Protocols
Mission Critical (MC)	74	59	49
Priority (Time Sensitive)	194	134	93
Priority (Not Time Sensitive)	65	53	38

- Time to IRB approval (TTIA) was reduced by **54 days** and time to activation (TTA) was reduced by **85 days** for MC protocols, compared to all Priority protocols.
- Our data indicates that the categorization of protocols was proven successful in effectively managing our activation timelines by allowing us to focus our efforts on the activation of MC protocols.
- In 2022, only 1 disease group went over their 2022 MC allocations.

Future Direction

After a year of categorizing protocols, we identified limitations which instructed our future goals:

1. MC investigator-initiated protocols (IITs) are unlikely to meet reduced activation goals due to factors specific to IITs (i.e., FDA submission requirements which adds at least 30 days, etc.). We are developing guidelines and adjusted goal timelines for certain IIT protocols.
2. Obtaining commitment from sponsors and PIs is critical for our MC timelines. We will continue to enhance this process.
3. Implementing MC specific activation requirements, such as finalized study manuals, to prevent delays in developing study tools and overall activation.