Protocol Categorization System to Improve Activation Timelines of Mission Critical Research

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1. Background
Memorial Sloan Kettering Cancer Center (MSK) activates over 300 prospective trials each year. Improvements to the time it takes to activate trials 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.

2. 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 studies critical to MSK's mission. The goal was to categorize protocols as:
- Mission Critical (MC): studies critical to our mission, for which our goal was to activate in a reduced amount of time
- Priority: all priority studies 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

3. Solutions and Methods
To operationalize this categorization system, leadership determined the monthly number of studies permitted to begin activation, based on the monthly number of studies 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.). 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.

4. Outcomes
Since the rollout of the categorization system, 186 studies were IRB approved, 123 of which have been activated. Our data indicate that the categorization of studies was proven successful in effectively managing our activation timelines. Time to IRB approval was reduced by 56 days and time to activation was reduced by 86 days for MC protocols, compared to all priority protocols.

5. Lessons Learned and Future Directions
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 add 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