Category: Trial Start-up and Activation – Completed Project

It's About Time: A Simplified Approach to NCI Trial Activation

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1. Background

As an NCI-Designated Comprehensive Cancer Center, Memorial Sloan Kettering Cancer Center (MSK) is committed to collaborations with NCI-sponsored research organizations to increase clinical trial availability to patients. A multistep review process and extensive list of operational items required to activate a study hindered our investigators' ability to provide new investigational treatments to their patients in a timely fashion.

2. Goals

Through the combined efforts of our local NCI group principal investigators, NCI network program, protocol activation and review cores, human research protection program, clinical research finance, and protocol operations, a plan was developed to simplify the activation process for trials in our NCI portfolio. Our goal was to improve the overall time to activation (OTTA), defined as the number of days from acceptance into the protocol activation and review cores to open to accrual (OTA) date, of NCI-sponsored trials while maintaining our high standards for regulatory compliance.

3. Solutions and Methods

To accomplish our goal, we identified five key study start-up requirements (i.e., eligibility checklist, sponsor-required regulatory documents, sponsor activation, initial protocol training, and study-specific contract, if applicable) needed to OTA. The remaining study start-up requirements (required for non-NCI protocols to OTA) needed to be initiated during the review process and completed within 45 days following OTA (or before the third enrollment). A streamlined review process (Figure 1), bolstered by communication with committees to emphasize short turnaround time, allowed for fast-tracked, concurrent department, committee, institutional review board (IRB) and privacy board (PB) reviews. OTTA was also cut significantly by using simplified standard language highlighting the importance of NCI trial participation in the research proposal submission form, eliminating service chief sign-off, and ensuring all collaborators adopted the new initiative. The goal OTTA using this new process was 15 days for all NCI-sponsored studies, with a "just-in-time" (JIT) mechanism to open trials within 2 to 5 days if an eligible patient was identified.

4. Outcomes

In 2021, following rollout on March 29, 13 trials opened under this initiative. Median OTTA was 14 days, including one study that opened in 4 days via the JIT mechanism, down from 90.5 days in 2020 (n=38 protocols) – an impressive 85 percent decrease in OTTA. The lesser number of protocols activated in 2021 was the intended result of levying a more selective approach to opening NCI-sponsored studies best suited to our patient populations. Overall, this initiative benefits MSK's patients, giving them access to important research studies quickly.

5. Lessons Learned and Future Directions

While we still encounter challenges meeting the 15-day timeline for trials requiring study-specific contracts and those requiring Institutional Biosafety Committee (IBC) review, the majority of our NCI-sponsored trials now open in 15 days or less. In 2022, we will explore ways to shorten the amount of

time needed for contract execution and IBC review in order to meet the 15-day turnaround for trials with these more complex requirements.

Figure: