Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

The Critical Role of Pre-Planning at Site Selection: Ensuring Adequate Resources and Preventing Activation Delays

N. Catti, A. Joshi, M. Huber, K. Kallas

Laura and Isaac Perlmutter Cancer Center at NYU Langone Health

1. Background

Since 2022, the Perlmutter Cancer Center (PCC) Clinical Trials Office (CTO) at NYU Langone Health (NYULH) has implemented several initiatives to reduce trial activation timelines. In Q3 of 2022, we introduced the Fast Track Program to expedite trials of high priority. High priority trials are defined as alignment with PCC's scientific mission, high unmet need or high enrollment potential. This program highlighted the need for a structed vetting process to align sponsor timelines with our activation goals. Based on its success, we expanded this process to trials with standard activation timelines.

2. Goals

The primary goal of this initiative was to preemptively identify and address potential roadblocks in the trial activation process to activate trials by 70 days post-Protocol Review and Monitoring Committee (PRMC) submission.

3. Solutions and Methods

To achieve this, we developed a set of tools to flag potential concerns:

- CTO routing form: A principal investigator (PI) assessment of the necessary resources for the clinical trial at the time of site selection.
- Sponsor intake questionnaire: Engages the sponsor to clarify expectations regarding the Clinical Trial Agreement (CTA) execution timelines, site initiation visit (SIV) scheduling, required credentialing and certification, study supply shipment expectations, upcoming protocol amendments that may affect the feasibility to conduct the trial, system accesses, and necessary ancillary approvals.
- PI intake questionnaire: Designed to identify prioritization of the trial, PI's commitment and availability to meet timelines and identify and financial conflicts of interest.

4. Outcomes

Through this structured intake and vetting process, we created a framework that ensures all stakeholders are aligned before trial activation. By understanding sponsor and PI availability, resource needs, and regulatory requirements early on, we created a timeline to ensure trials are activated promptly. This proactive planning addressed potential barriers and improved execution during trial initiation.

The implementation of these pre-planning steps has significantly streamlined the trial activation process, resulting in shortened activation timelines. In 2024, the median activation time was reduced to 65 days post-PRMC submission, a marked improvement from 203 days in 2020, before the adoption of these vetting processes. Of the trials activated, approximately 19 percent participated in the Fast Track Program, achieving a median activation time of 40 days post-PRMC submission, which included the accelerated activation of a complex cell therapy trial. The early identification of potential roadblocks facilitated more efficient troubleshooting, contributing to faster trial initiation. Furthermore, the intake process improved communication and collaboration between the CTO, sponsors, and PIs, leading to a more cohesive and efficient approach to trial setup.

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

5. Lessons Learned and Future Directions

Our experience with the Fast Track Program and pre-planning for standard activations highlighted key lessons. First, early alignment between sponsors and site teams is essential to prevent startup delays. Second, a standardized intake process helps reduce the risk of overlooked issues that may impact timelines. Moving forward, we plan to refine the vetting tools, especially the sponsor and PI intake questionnaires, to address challenges identified during the program rollout. We will also continue to monitor activation times and adjust our approach based on feedback to further improve trial startup efficiency.