Sprinting to the Finish Line: Implementing a “Fast Track” Program to Expedite High Priority Clinical Trials at an NCI Designated Comprehensive Cancer Center

NYU Langone Health

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

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Background

The Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) is an NCI Designated Comprehensive Cancer Center. Activating a clinical trial at PCC, a matrix center, is complex and involves multiple staff and departments across the enterprise and the study sponsor. As a NCI Designated Comprehensive Cancer Center, studies are expected to activate under 100 days from submission to the scientific review committee. In 2022, the PCC Clinical Trials Office (CTO) implemented several new processes, workflows, and staffing changes, improving the overall median activation timeline to 71 days from submission to the Protocol Review Monitoring Committee (PRMC). During this period, the PCC CTO also launched a “Fast Track” program to expedite the activation of high priority clinical trials. High priority trials are defined as having high accrual potential, linked to PCC science, PI is an author/on steering committee, or high unmet patient need. Each clinical trial undergoes a 2-stage review: 1 – Disease Management Group (DMG) and 2 – PRMC.

Goals

Our goal for all interventional treatment trials is to activate within 90 days of submission to the PRMC. The goal for fast track studies is to activate interventional treatment trials within 42 to 56 days of submission to PRMC, measured from PRMC submission through the date the study was opened to enrollment by PCC CTO.

Outcomes

We successfully activated our first pilot study **33 days** following PRMC submission. By the end of Quarter 2 in 2023, 8 additional studies have been activated with an overall median of **45 days**, range of 26-61 days. All studies are industry sponsored trials. Of the 6 studies activated within our goal, PCC was able to have the 1st patient enrolled on 4 of these studies; all of which are early phase trials with competitive slot enrollment. 7 of the 9 studies are early phase trials. One of the early phase trials was a solid tumor cellular therapy trial requiring Institutional Biosafety Committee Review. This program has proven to be successful and increases patient access at PCC. The portfolio of these trials also indicate that we can activate a trial of any complexity through this mechanism if it is a high priority and if we have sponsor commitment.

Disease Management Group	Phase	Time from PRMC to Study Activation (Days)
GI	1b/2	33
Thoracic	3	59
Phase I	1/2	61
Hematologic	1/2	59
GU	1	45
GYN	1/2a	26
Melanoma	3	46
Phase I	½	28
Phase I	1	42
Median		**45** (26-61)

Solutions and Methods

The CTO met with all internal stakeholders across the enterprise to discuss feasibility, eligibility of trials, capacity, and the need for sponsor commitment to implement this program successfully. Five key components and parameters were identified to achieve this goal: Clinical Trial Agreement (CTA), Institutional Review Board (IRB), Site Initiation Visit, System Access, and Vendor supplies. In addition, we developed service level expectations (SLE) for NYULH staff and for the sponsor. Before agreeing to fast track a study, we required sponsor commitment to our SLE and evaluated our internal workload and capacity. Once a study is confirmed to go through this mechanism, a timeline with target dates are projected and e-mailed to all responsible parties. A regulatory manager assigned to pre-activation regularly monitors the progress of the trial and escalates when any component is at risk of not meeting target.

Lessons Learned and Future Directions

While these activation timelines are excellent, some delays could have been avoided (e.g., the study sponsor being unwilling to schedule SIV before CTA execution, the investigator being out of office during a critical time, delayed radiation safety approval, and vendor issues). As a result, we developed a sponsor and investigator intake form and revised specific processes to start earlier to mitigate these potential barriers. The future direction is to develop strategic partnerships with the sponsors we often work with to enable the automatic application of the fast track program with a master CTA, budget, and informed consent. We will continue to revise our procedures as we learn valuable lessons during this process. Additionally, with high demand for the fast track program, we are planning for a dedicated fast track manager in the next fiscal year.