Category: Trial Start-up, Activation, and Protocol Development – Completed Project

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

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1. 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. In 2022, the CTO implemented several new processes, workflows, and staffing changes, improving the overall median activation timeline to 71 days. During this period, the PCC CTO also launched a "Fast Track" program to expedite the activation of high priority studies. These studies have high accrual potential, are linked to PCC science, PI is an author/on steering committee, or high unmet patient need. Each clinical trial undergoes a two-stage review: 1 – Disease Management Group (DMG) and 2 – Protocol Review and Monitoring Committee (PRMC).

2. 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.

3. 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.

4. Outcomes
Our first pilot study was successfully activated 33 days following PRMC submission. Four additional studies were activated. The median time to activate was 59 days, ranging from 33 to 61 days. Two additional studies are in progress and expected to activate in under 42 days.

5. 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.