Timing is Everything! Reducing Clinical Trial Activation Timelines 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 intricate; at a minimum, it involves staff from the Clinical Trials Office (CTO), departments across the institution, and the study sponsor. During the COVID-19 pandemic, the CTO experienced increased study activation times. The median time to activate an interventional treatment study from submission to the Protocol Review and Monitoring Committee (PRMC) was 203 days in 2020, 113 days above our target of 90. Timely activation of trials is critical to offer timely treatment options to patients, maximize enrollment to study, and fulfill industry sponsors' rigorous start-up timelines.

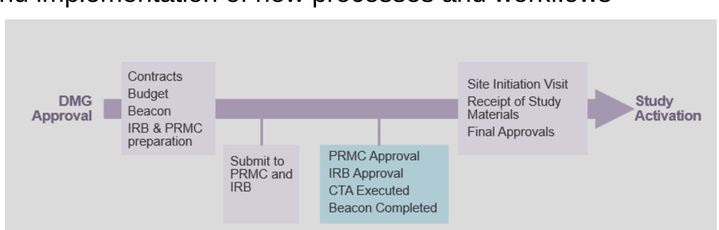
Goals

The goal was to achieve a median of 90 calendar days by the end of 2022 for all interventional treatment studies prospectively submitted to PRMC in 2022 by the PCC CTO. The timeline started at PRMC submission and ended when the study was opened to enrollment by the PCC CTO.

Solutions and Methods

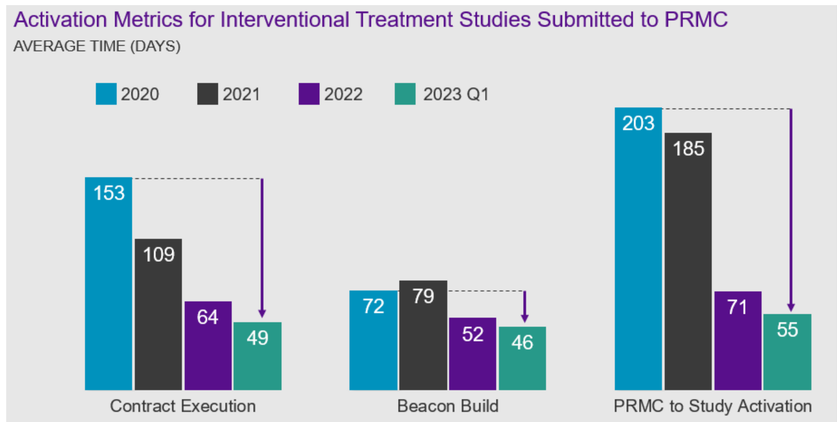
A Study Activation Task Force was assembled to identify bottlenecks and improve processes. The multidisciplinary team included CTO leadership and representatives from the NYULH Office of Science and Research (OSR) and Investigational Pharmacy. Specifically the following interventions were implemented:

1) Developed an internal activation dashboard to monitor and produce reports on study activation timelines
2) Increased staffing for contracts, investigational pharmacy informatics, and pre-activation regulatory
3) Maintained rigorous weekly meetings to review each study in the pipeline and identify any barriers
4) Established Service Level Expectation (SLE) for each activation component and establish an escalation policy to Deputy Director of PCC when SLE is not being met or at risk for not being met
5) Developed an intake questionnaire for Sponsors prior to PRMC submission to identify potential barriers in timely activation and receive sponsor commitment to adhere to PCC CTO SLE
6) Utilized a contract agency to source trained regulatory staff and increase compensation/benefits to stabilize turnover
7) Initiated all sub-processes after the Disease Management Group (DMG) approval instead of after PRMC approval
8) Restructured regulatory management to assign a dedicated pre-activation manager and liaison across the enterprise
9) Limited new studies in Q1 of 2022 to allow for staff stabilization and implementation of new processes and workflows



Outcomes

At the conclusion of 2022, our median activation timeline was **71 days** (range 28-268), surpassing our goal of 90 days by 21 percent. 2023 median number is projecting under 60 days.



Lessons Learned and Future Directions

To keep the activation timeline down, rigorous oversight is necessary. This requires a dedicated pre-activation manager, weekly oversight and robust escalation policies in place. The intake questionnaire was also critical to identify barriers and engage sponsor commitment. Our future goal is to decrease the time from DMG approval to PRMC submission.