Category: Trial Start-up and Activation – Work in Progress

Process Improvements to Shorten Clinical Trial Activation Times Within a National Cancer Institute-Designated Comprehensive Cancer Center

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1. Background

Lengthy clinical trial activation times limit patients' access to novel treatments, delay trial completion, and frustrate sponsors, investigators, and administrators, yet delays remain ubiquitous. When the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) surveyed its members, average activation time was approximately 180 days, well beyond the desired 90-day activation time expected by reviewers evaluating National Cancer Institute (NCI)-Designated Cancer Centers. After repeated attempts to improve existing processes, the Clinical Protocol and Data Management service (CPDM) at Wake Forest Baptist Comprehensive Cancer Center (WFBCCC), an NCI-Designated Comprehensive Cancer Center, undertook a ground-up evaluation and revision of its activation processes to improve trial activation.

2. Goals

In collaboration with WFBCCC leadership and relevant stakeholders, including faculty, the institutional office of sponsored projects (OSP), and institutional clinical trials office (CTO), and with the cooperation of the institutional review board (IRB), CPDM initiated a 90 Day Challenge with the goals of reducing the median time to activation, measured from the time of submission to the Protocol Review Committee (PRC) to trial activation to under 90 days.

3. Solutions and Methods

After a review of trials activated in the preceding 12 months, sources of delay were identified, and workflow was revised to address these delays. Specific problems included incomplete PRC submissions, a failure of investigators to adequately address operational deficiencies prior to PRC submission and excessively long delays in the performance of various stakeholders' tasks. Changes to address these problems included the creation and empowerment of a CPDM Feasibility Group (CPDM-FG) comprising CPDM clinical, data and regulatory staff, representatives from nursing, pharmacy, pathology, medical oncology, minority health care equity and others, to ensure that all operational issues and impediments are addressed, and all required documentation is in order prior to PRC submission. Workflow changes include running activation steps in parallel and earlier in the activation process, initiating them immediately after PRC approval. Further, strict mandatory timelines were implemented and enforced for all internal stakeholders throughout the activation process with a particular emphasis on contract and budget negotiations. Currently, the entire activation process is tracked, including details about document exchanges and hand-offs between various stakeholders, both internal and external. Weekly meetings within CPDM and with OSP and CTO occur to identify and address delays exceeding the prescribed times.

4. Outcomes

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To date median times from PRC submission to PRC approval, PRC submission to IRB approval and PRC submission to trial activation have markedly improved and now meet and exceed NCI metrics for trial activation times with a median time of activation of 72 days. Investigator and staff satisfaction is improved, and resources are being used more efficiently.

5. Lessons Learned

Dramatic improvement in trial activation times is possible. Although the process can be resource intensive and necessarily require the cooperation and collaboration of all stakeholders for maximum benefit. We continue to revise our processes based on ongoing evaluation and are looking to greater engagement with external partners to ensure continued improvement in trial activation times.