Category: Trial Start-Up and Activation – Completed Project

Strategies for Improving Time-to-Activation of Clinical Trials

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1. Background

Delays in clinical trial activation can impede availability of novel therapies, combination regimens, or innovative patient care. Various steps in trial establishment processes obstruct timely activation, including time required for contract and budget negotiation, institutional review board acceptance, number of committees requiring approval prior to study initiation, and scheduling site initiation visits. To address these challenges, strategies need to address both sponsor-institution interactions and intra-institutional procedural obstacles. We sought to reduce our time to activation by identifying, understanding, and resolving redundant and inefficient procedural activities.

2. Goals

Our short-term target for trial activation time was 120 days with a 90-day final goal. A task force of senior institutional leadership was established in 2017 to achieve this goal. We reviewed and documented all steps in the current process, which were comprehensively analyzed to eliminate redundancy, revise workflows, start simultaneous processing of multiple regulatory and internal processes (including IRB and coverage analysis), and review pending studies monthly by disease center teams. We implemented automated reminders in the clinical trial management system (CTMS) to alert involved staff when a step approaches the allocated processing time. Management also receives monthly reports to monitor progress and intervene as necessary.

3. Solutions and Methods

The task force meets quarterly to review the trial activation process. Monthly reviews of pending trials for intellectual property (IP) and risk issues were instituted. Our clinical trials management application (CTMA) for metrics-based tracking of trial procedures tracks time spent on each component of the activation process, with email alerts sent to personnel at designated threshold periods. Furthermore, eReg software and eSignature tool were implemented to accelerate activation processing. The Clinical Protocol and Data Management (CPDM) assisted study cost out and preparation of source documents and orders commences immediately after protocols are submitted to the protocol review committee (PRC).

4. Outcomes

Our CTMS program enabled us to identify trials and sponsors that challenge trial activation the most, and the task force developed individually tailored mitigation strategies. CTMS enhancement allows calculation of the complexity of new protocols and required CRS staff workload for efficient trial performance, which is expected to reduce planning time for every new trial. The implemented continuous improvement approach reduced activation times by 19 percent and 62 percent for all adult and national protocols, respectively and the overall reduction from 2018 to 2020 was approximately 21 percent.

5. Lessons Learned

Steps implemented by the task force that substantially reduced trial activation delays include conducting regulatory, legal, and contract reviews simultaneously following protocol approval by the PRMC/PRC and streamlining reviews by the radiation safety committee whenever appropriate. The simultaneous submission of protocols to the IRB and IND applications to the FDA also reduced activation times. This division of processes reduced median activation times for industry, national, and external-peer reviewed trials by 29 percent, 62 percent, and 43 percent, respectively. Implementing this strategy from July 2017 to December 2020 overhauled, redesigned, and vastly improved our trial activation process, thereby providing a platform to ensure the gains and advances accomplished are maintained and built upon.