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

FastTrack: A Pilot Project to Shorten Activation Times

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1. Background

At Medical College of Wisconsin Cancer Center (MCWCC), new protocols approved for activation must complete multiple, time-consuming steps before they can be opened to accrual. In addition to the scientific review imposed by MCWCC, trial documents must receive approval from external sponsors and all relevant institutional committees, such as the institutional review board (IRB), safety committees (radiation and biosafety), and the hospital's Office of Clinical Research and Innovative Care Compliance (OCRICC). Our activation times have worsened during the COVID-19 pandemic due to staffing issues within our Clinical Trials Office (CTO) and across our institutional partners.

2. Goals

Our goal was to develop a FastTrack pilot program to open select trials within 60 days of SRC submission. By implementing this pilot, we hope to open high priority trials quickly, reduce our overall activation timeline, and most importantly, identify potential process changes that could create timeline-shortening efficiencies for all the trials in the activation queue.

3. Solutions and Methods

We took a three-pronged approach to implement FastTrack. First, we worked with our hospital and institutional partners to get their buy-in to accelerate their processing of FastTrack protocols. Most notably, the IRB allowed a date for project review to be selected prior to the IRB application being completed and submitted. Second, we introduced the process to our Disease-Oriented Teams (DOTs), who would be nominating protocols for FastTrack. We asked them to choose protocols of high clinical/academic importance, high accrual potential, and commitment from the sponsor and PI to be responsive during the accelerated activation process. DOTs were selected on a rotating basis which allowed all to participate. Lastly, we formed a core CTO group that meets weekly to review where the FastTrack protocols are in activation and troubleshoot delays.

4. Outcomes

The first protocol entered the FastTrack program in March of 2022. Since then, we have opened seven FastTrack protocols with a mean activation time of 98 days (median of 85 days; range of 42 to 193 days) from SRC submission to open to accrual. This includes two cooperative group, three industry, and two institutional trials. Over the same time period, activation of non-FastTrack trials averaged 283 days.

5. Lessons Learned and Future Directions

The importance of having all regulatory and study documents available prior to the initiation of the FastTrack process is critical. This allows all involved to begin review at the same time. Weekly communication between team members allows for quick resolution or escalation of issues.

Moving forward, FastTrack trials will only include industry and institutional trials. Since all DOTS have had the opportunity to FastTrack, preference will be given to studies that are high priority and have a high accrual potential. The core CTO group is now meeting twice monthly with every DOT manager to review the entire portfolio in activation for that DOT.