



FastTrack: A Pilot Project to Shorten Activation Times

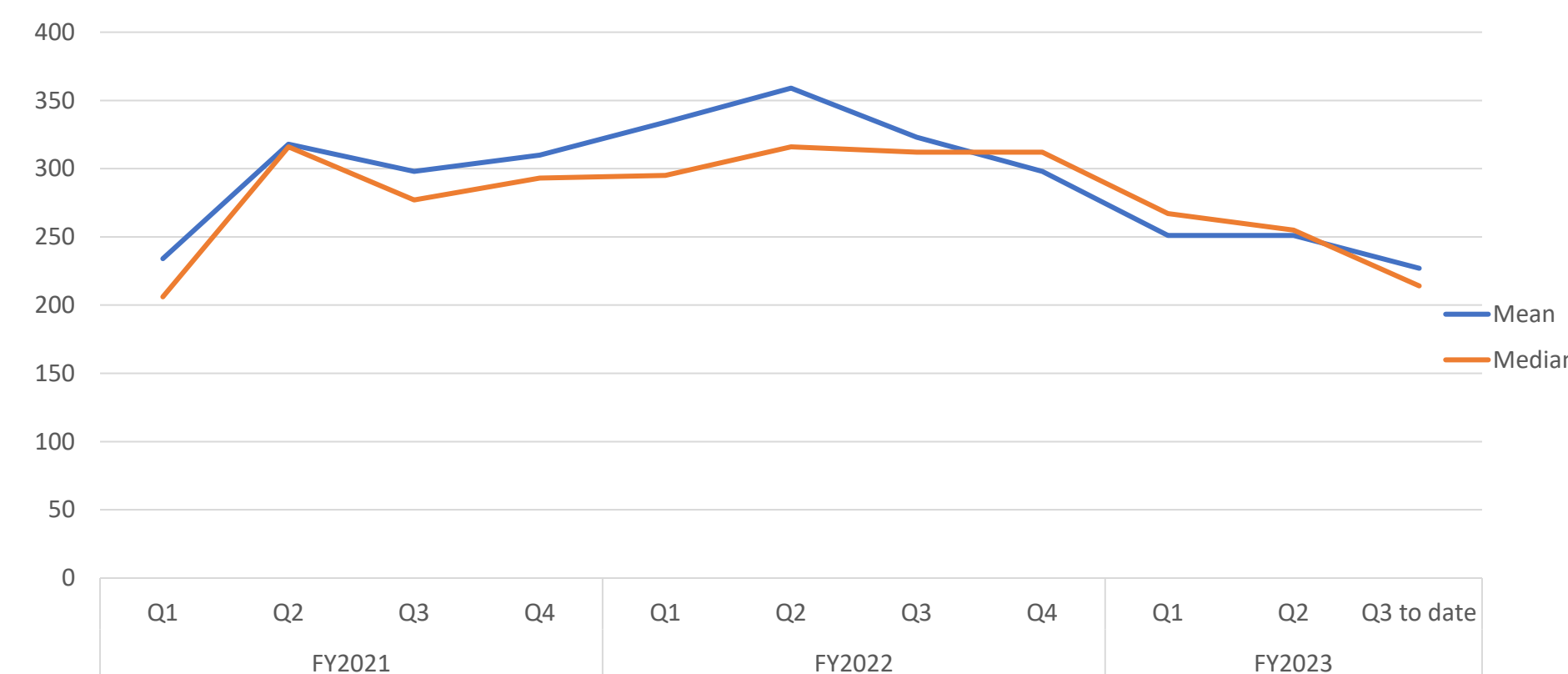
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Background

At Medical College of Wisconsin Cancer Center (MCWCC), new trials approved for activation must complete multiple, time-consuming steps before they can be opened to enrollment. In addition to all the sponsor mandated requirements and budget/contract negotiations, trials must receive approval from all relevant institutional committees. This includes review by Scientific Review Committee (SRC), Operational Feasibility Committee (OFC), Institutional Review Board (IRB), safety committees (radiation and biosafety), and the hospital's Office of Clinical Research and Innovative Care Compliance (OCRICC). Not all these reviews are done in parallel. Our activation times worsened during the COVID-19 pandemic due to multiple factors, but most notably related to staffing issues within our Clinical Trials Office (CTO) and across our institutional partners.

Adult CTO activation timelines by quarter



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 hoped 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.

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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 trials. 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 trials for FastTrack. We asked them to choose trials 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 met weekly to review where the FastTrack trials were in activation and troubleshoot delays.

Outcomes

The first trial entered the FastTrack program in March of 2022. Since then, we have opened seven FastTrack trials 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. The largest impact in timeline was noted in the submission to OCRICC from SRC approval. The average timeline to OCRICC submission of non-FastTrack trials is 134 days. The average timeline to OCRICC submission of the FastTrack trials was 25 days.

Protocol type	Accrual to Date	SRC Approval to OCRICC Submission (Days)	Submission to OCRICC to OCRICC Approval (Days)	Start IRB Submission to IRB Approval (Days)	IRB Approval to Open Accrual (Days)	Total Days in Activation
Industry- Early Phase	8	11	24	50	15	64
Industry-Cell Therapy	19	22	43	69	3	80
Industry-Cell Therapy	0	18	49	75	64	128
NRG-GU	1	22	20	29	1	42
HCRN-Breast	0	31	46	141	32	193
NRG-CNS	0	23	20	75	8	91
IIT-Early Phase	6	49	15	39	1	85

Lessons Learned

The importance of having all regulatory and study documents available prior to the initiation of the FastTrack process was critical. This allowed all involved to begin review at the same time. SRC approval has been the date used to begin all regulatory and budget work in the current workflow. With FastTrack trials, the regulatory team and finance team began this work the moment the study documents were available. Weekly verbal communication between team members (many of which work remotely), including operational and physician leadership, allowed for quick resolution or escalation of issues. The experience of the team members working on the FastTrack trial was also key to the success of activation.

Future Directions

- FastTrack trials will only include industry and institutional trials. The impact of shortening activation timelines in cooperative group trials was not felt to be as significant as those trials generally tend to activate faster.
- 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 institution is considering a tiered approach to trial activation.
- The core activation group (research manager, regulatory coordinator, financial assistant, operations representative, and the OCRICC representative) is now meeting twice monthly to review the entire portfolio in activation for that DOT. This has helped identify gaps, protocol version discrepancies, and operational delays. This has also helped inexperienced staff understand all the steps in trial activation. These meetings have been well received by all groups and will continue.
- Since we have all documents at the onset of the activation process, we are looking at initiating the financial, contractual, and regulatory work prior to the SRC submission.