Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Fast Track: Fine-Tuning an Accelerated Activation Program

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1. Background

In clinical research, timely trial activation is critical to ensure efficient patient access and enrollment. Lengthy activation time is often the result of bottlenecks including multiple committee reviews, contract and budget negotiations, and workflow inefficiencies. To help address these challenges, in 2022 the Perlmutter Cancer Center Clinical Trials Office at NYU Langone Health implemented an accelerated activation option (Fast Track) for select industry-sponsored trials.

2. Goals

The primary goal of this initiative is to fine-tune the process involved in selecting trials for Fast Track activation and to optimize workflows involved in the startup process to ensure that Fast Track trials are activated within the targeted activation time.

3. Solutions and Methods

Two key strategies were implemented in order to better optimize use of the Fast Track accelerated activation program:

1. **Intake questionnaire**: An intake questionnaire was developed to establish service level expectations for key components in study activation and ensure sponsor adherence to these expectations. This list of questions is sent to sponsors and responses are assessed before a study is confirmed to utilize Fast Track. Questions are aimed to target anticipated bottlenecks and problem areas in the startup process. Additionally, as new issues have been identified during startup, new questions have been added as a preventative measure for future trials. Questions target multiple areas including but not limited to: contract/budget negotiations, study timelines, anticipated regulatory document turnaround times, and special training and/or credentialing requirements. Dates for startup milestones are also outlined and must be agreed to. Lastly, the Principal Investigator answers a separate list of questions aimed to justify use of Fast Track activation.
2. **Personnel allocation:** To ensure that trials selected for Fast Track activation receive the required time and effort to activate within the target timeframe, two personnel-focused approaches are used. The implementation of floater Pre-Activation Specialists ensures that regulatory staff's bandwidth is accounted for and that workloads remain manageable. Additionally, a dedicated Fast Track Manager was hired to maintain oversight of Fast Track trials.

4. Outcomes

To date, 38 trials have been activated through the Fast Track program with a median activation time of 40 days (range: 26-61) compared to 70 days (range: 24-307) for standard industry-sponsored trials activated in the same timeframe. Of these 38, 24 were activated within the target of 42 days or less and for seven trials NYU enrolled the first patient study-wide. By optimizing processes involved in our Fast Track accelerated activation program, we have consistently activated these trials within target timelines. Further fine-tuning these workflows will continue to ensure the success of the program.

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5. Lessons Learned and Future Directions

Our accelerated activation program has proven to be an attractive option for sponsors interested in activating trials at a major academic university setting well under standard timelines. By continuing to optimize the program, we hope to see additional participation from sponsors and increase the number of trials utilizing Fast Track per year. This approach offers a model for other institutions seeking to adopt an accelerated activation program or to further optimize their existing program.