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

Shorter Activation Timelines are Associated with Improved Enrollment Efficiency

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1. Background

In clinical research, the timely activation of trials is critical to ensure efficient patient enrollment and maintain the continuity of study operations. Lengthy activation processes can contribute to delayed patient enrollment and reduced study timelines. Reducing time to activation is a key objective for cancer hospitals aiming to accelerate the availability of innovative treatments while improving operational efficiency. In recent years, the Perlmutter Cancer Center Clinical Trials Office at NYU Langone Health has worked to overcome these challenges by refining workflows and optimizing internal processes, aiming to shorten trial initiation times and enhance enrollment potential.

2. Goals

The primary goal of this initiative was to reduce trial activation timelines.

3. Solutions and Methods

In order to reduce the time of clinical trial activations, we employed the following methods:

1. Streamlining activation processes: Identifying and eliminating bottlenecks in the trial initiation timeline, including improving workflows and promoting coordination across departments.
2. Implementing data-driven approaches: Using performance metrics and data analysis to monitor timelines, predict potential delays, and proactively address issues.
3. Expanded staffing: increased number of full-time pre-activation regulatory specialists available to handle study activations.
4. Fast Track program: implemented new process by which selected trials may undergo accelerated activation.

4. Outcomes

By refining internal workflows, we successfully reduced the time from trial initiation to activation. This was associated with a decrease in the time from study activation to first patient enrollment. These improvements not only enhanced operational efficiency but also contributed to the hospital's ability to provide cutting-edge treatments to patients sooner.

5. Lessons Learned and Future Directions

Our experience with accelerating activation time has shown to directly benefit the enrollment potential of clinical trials. By continuing to optimize our workflows, we aim to further reduce activation time for clinical trials in order to improve patient access to cutting-edge treatments and enhance the overall efficiency of clinical research. This approach offers a model for other institutions seeking to enhance clinical trial timelines and patient access to innovative therapies.

Figure

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Table 1: (By year) Time to activation versus time to first patient enrollment

Year	Activation time (days)		Activation to first patient (days)	
	Median	*Mean*	*Median*	*Mean*
2020	202	222	59	119
2021	191	208	84	117
2022	70	76	58	98
2023	65	76	67	105
2024	60	69	54	62