

The Race Against Time: Sylvester Trial Activation Reduction Time (S.T.A.R.T.)

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1. Background

Opening clinical trials in a timely fashion allows patients with limited treatment options earlier access to clinical trials. Clinical trial activation is a complex process involving multiple stakeholders across the University and Sylvester.

We detected a steady increase in Trial Activation Time (TAT) in previous years with a high of 216 calendar days in Fiscal Year 2022. As a result, we created the “Sylvester Trial Activation Reduction Time (S.T.A.R.T.) Initiative” in Fiscal Year 2023.

2. Goals

To decrease trial activation time to a median of 90 calendar days and increase efficiency by streamlining processes and working in simultaneous batched workflows.

3. Solutions and Methods

- Created an ideal state with new and simplified batched process workflow with a new target of 90 calendar days TAT (median) across all industry studies.
- Held a Kaizen event to present ideal state to key personnel and process stakeholders to collect feedback and to identify barriers.
- Developed a portfolio of 36 projects based on the identified barriers with the intent to improve efficiency with support from the Sylvester project management team.
- Created a diagram aligning projects to key stakeholders in each process and engaged them in problem solving.
- Implemented new activation process (Final State) while improving internal and University collaboration to improve TAT.

4. Outcomes

- After S.T.A.R.T. launch, we achieved a reduction from 279 calendar days (baseline = Quarter 2, Fiscal Year 2023) to 112 calendar days median Trial Activation Time for the current quarter (Quarter 2, Fiscal Year 2024)
- TAT 60 percent reduction from baseline
- Number of trials open per quarter remained consistent
- The number of clinical trials activated in ≤ 90 days grew by 700 percent after the S.T.A.R.T. initiative launch

5. Lessons Learned and Future Directions

Improving clinical trial start up is a balance of meeting sponsor expectations, remaining competitive with comparable cancer centers, and evaluating the internal needs of our stakeholders. The project is not yet complete. We will continue to identify and work on new projects identified through the initiative.

Key components of the S.T.A.R.T. initiative moving forward include:

- Establishing a clinical trial start-up team
- Developing a rewards and recognition system for meeting or exceeding targets

Category: Trial Start-up, Activation, Regulatory, and Protocol Development - Work in progress

- Increasing catchment area relevant and programmatically aligned protocols to increase prioritization