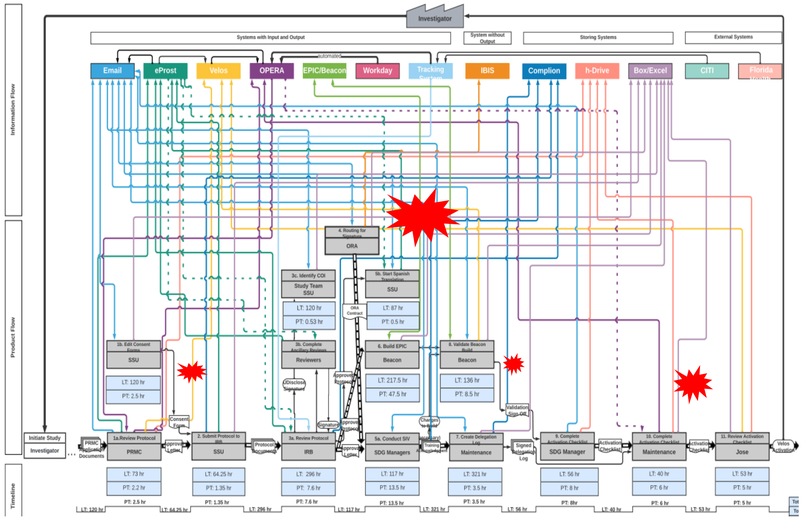
Sylvester Trial Activation Reduction Time (S.T.A.R.T.) Initiative

Lindsey Mooney, Laura Thyssen, Sergio Cardona, Silvia Garcia, Gabriel Diaz, Kelly Williams, Philip Arlen, Josefina Sanchez, Kelly Hearne
Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine

BACKGROUND

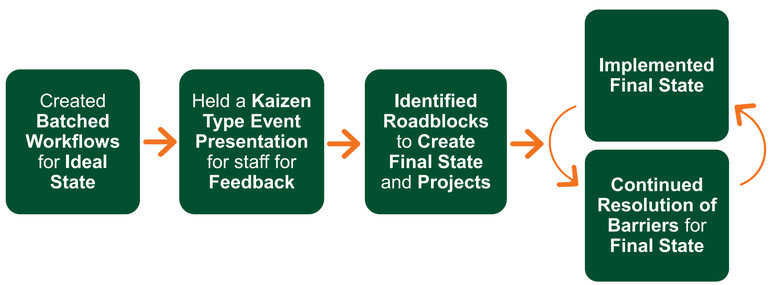
It is critical to open new clinical trials as quickly and efficiently as possible and to provide patients access to the best possible treatment options. Clinical trial start up is an extremely complex process that transpires across multiple positions, departments, organizations and systems as shown below. We hypothesized that by streamlining these processes and working in simultaneous batched flows, we can eliminate bottlenecks in the highly complex activation process.



This value stream map demonstrates the complexity of the process and visualizes where bottlenecks in the process occur.

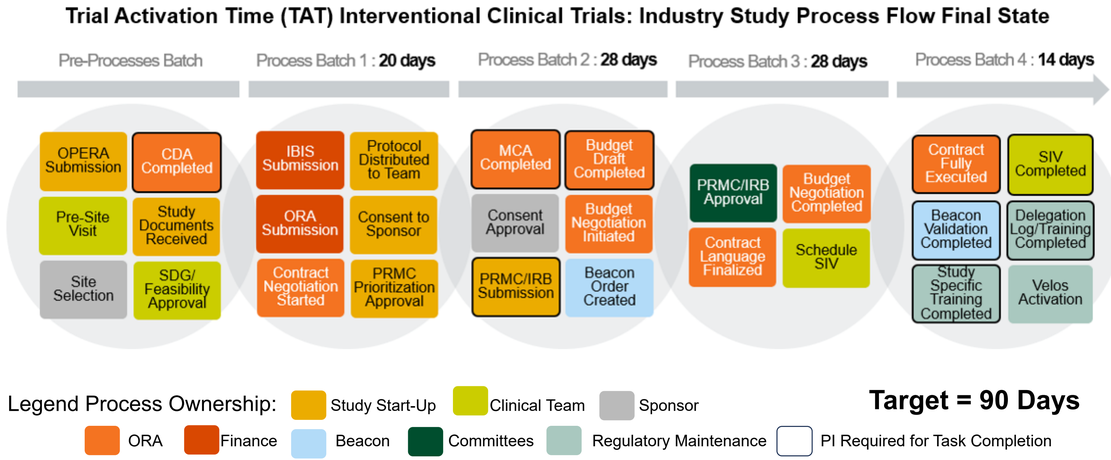
OBJECTIVE

The objective of the **S.T.A.R.T.** initiative was to understand the current state and implement a streamlined trial activation workflow designed to reduce the median Trial Activation Time (TAT) to our target of 90 calendar days.



METHODS

- Created an ideal state to present to key personnel and process stakeholders
- Replaced current linear workflow with new and simplified batched process workflow with a new target of 90 days TAT (median) across all trial types
- Held a Kaizen event to collect feedback for the new process to identify barriers
- Developed a portfolio of projects intended to improve TAT efficiencies with support from the Sylvester Research project management team
- Created a diagram aligning projects to key stakeholders
- Implemented new activation process while improving internal and University collaboration to improve efficiencies



Office of Research Administration*

- Escalation SOP
- Weekly meetings
- Master agreements
- ORA dashboard
- Training on Cancer SOC
- Create list of difficult sponsors/ CROs

Clinical Team

- SIV scheduling trigger
- SDG quorum list
- Tiered budget for research lab
- SDG IBIS submission
- Redefine SDG leadership roles
- Velos access list
- CRS manuals
- Weekly SIV blocks

Committees

- Eliminate backlog of FRC/ PRMC
- Increase FRC slots
- Increase PRMC slots

Study Start-Up

- Submit to ORA after PRMC Prioritization
- FRC review prior to SDG review
- Revise consent template
- Redefine study start up team
- Create site activation process
- Create a sponsor welcome packet
- Expand activation checklist capabilities

Regulatory Maintenance

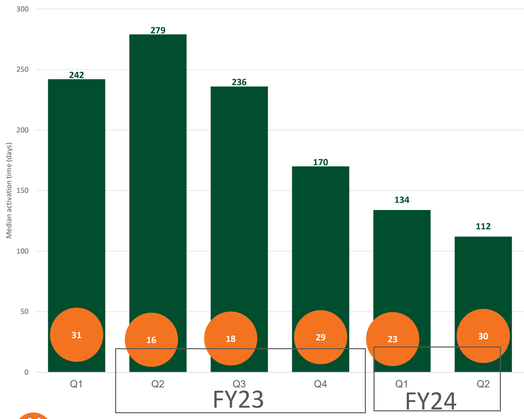
- Delegation log template
- Regulate staff training

General

- Immobilization of studies in the pipeline
- Multiple systems
- Expectations of PI
- Move CDAs to SCCC
- Eliminate protocol amendments during activation
- Increase staffing
- Streamline feasibility
- Credentialing dashboard
- Admin days
- Document processes

OUTCOMES

- After **S.T.A.R.T.** launch, reduction from 279 calendar days (baseline = Q2, FY 2023) to 112 calendar days median Trial Activation Time for the current quarter (Q2, FY 2024)
- Trial Activation Time 60% reduction from baseline
- Number of trials open per quarter remained consistent
- The number of clinical trials activated in ≤ 90 days grew by 700% after launch



FUTURE PLANS

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
- Increasing Catchment Area relevant and programmatically-aligned protocols to increase prioritization