Accelerating Cancer Research Trial Startup In The Community Setting: A Quality-Improvement Study

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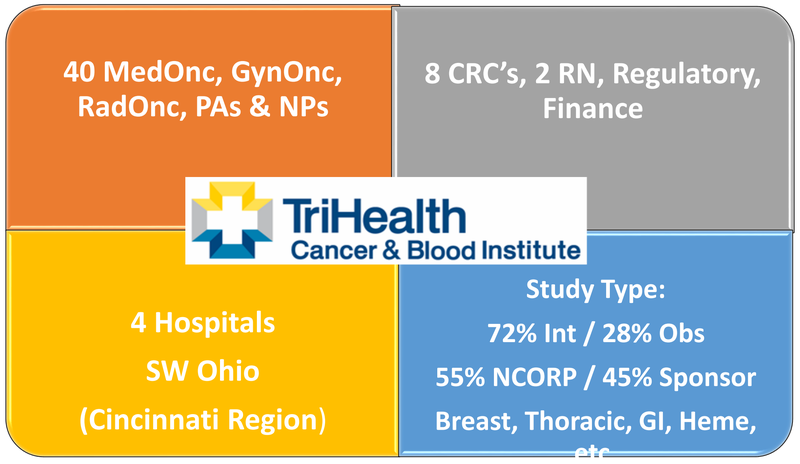
INTRODUCTION

There is **large variation in activation times** for cancer clinical trials.
This **delays patient benefit** from cutting edge treatments.
Typical **academic medical centers take longer** to activate a clinical trial vs. community settings.
By **adopting quality improvement processes,** they reduced clinical trial start-up time.
TriHealth Cancer & Blood Institute (TCBI) adopted these same processes in the community setting for further improvement.

Figure 1. TCBI Overview



METHODS

A multi-diciplinary team was created to further **investigate** areas of inefficiencies in critical areas of feasibility, contract review/negotiations, budget negotiations, IRB, regulatory/compliance, and study activation.
Swim lanes helped identified areas of backlog and/or barriers to being efficient. Example CTA originally could have up to 32 touches and taking up to five months before execution.
Utilized the **PDSA model** in mapping TCBI's improvement process to carry out change.
Internal **Committees and Conferences** such as Molecular Tumor Boards, Scientific Review Committee, Thoracic Conference, Breast Committee, GI Tumor Board, Multi-disciplinary clinic conferences are some of the areas that were tested for data collection related to startup times.

METHODS (continued)

Study encompassed **July 1, 2022, to June 30, 2023**.

Baseline data: January 2021 to December 2021 with

Mean clinical trial start-up time = 116 days.

Used a **swim-lane process** to define typical steps and stakeholders for clinical activation time at our institution **prior to the study time** (Figure 2).

Used **Plan-Do-Study-Act (PDSA)** to identify experts in respective areas of the workflow process and **gave** them **ownership** of that process (Figure 3)..
Tested out a more **streamlined workflow process.**

Figure 3. PDSA

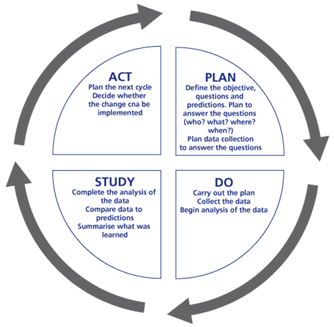
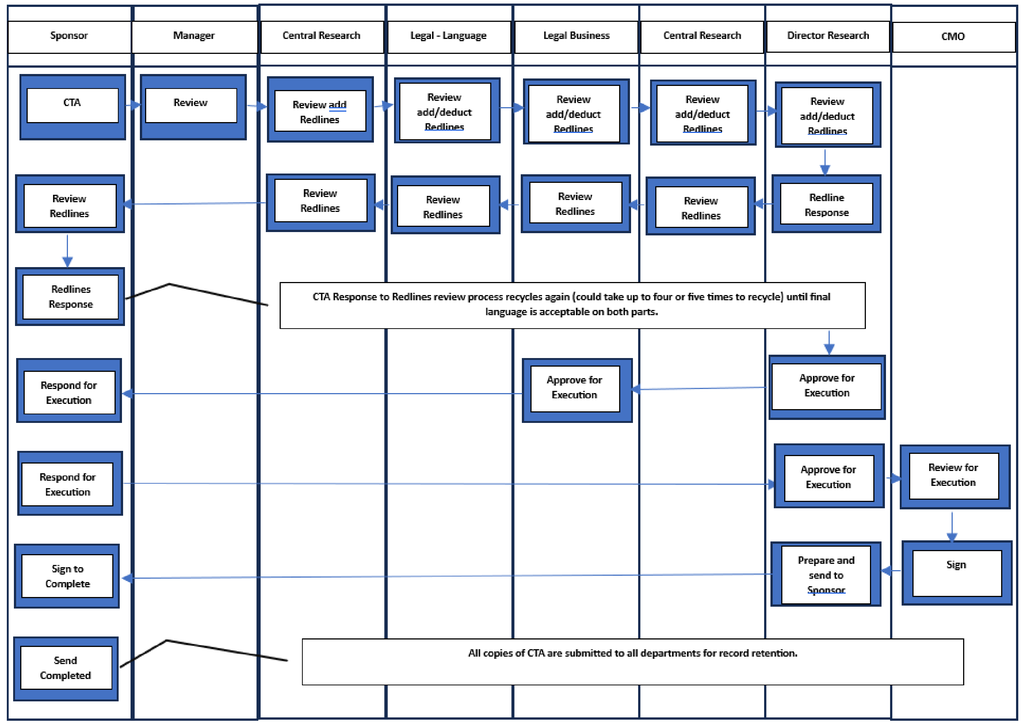


Figure 2. Example Previous CTA Workflow



RESULTS

For Jul 2022 to Jun 2023, we demonstrated a **44% reduction** in clinical trial start up time (141 days to 79 days).
We doubled the number of active trials.
This change resulted in sustainability that carried into the subsequent year (2023) by reducing start-up time to 70 days.

SUMMARY & CONCLUSIONS

Using improved processes, we **can open a study in 2 months** which **previously took 4 months.**
We increased enrollment by **24%.**
This has allowed **a shift to investigational trials** from non-interventional trials

FUTURE DIRECTIONS

Expect further improvement with a Just-in-Time program (**TIME Program**) using enhanced patient ID and enrollment in TCBI trials *(see Abstract #1553).*

Figure 4. Comparison of Reduction of Time

Academic vs Community	Prior to Process Improvement (Days)	After PI (Days)	Method	% Reduction
Academic				
AMC #1	**77**	**55**	**Doubling Capacity Contract & Budget Negotiation**	28%
AMC #2	**189**	**59**	**Plan-to-Do-Act, Six Sigma, Lean 3 P**	66%
AMC#3	**185**	**132**	**Parallel Processing & Cross-Training**	28%
Community				
TCBI Year 1	**141**	**79**	**Improved WorkFlow (decreased touches)**	**44%**
TCBI Year 2	**141**	**70**	**Applied Team Education**	**50%**

The Academic Medical Centers
AMC#1 – Univ of South Florida Activating clinical trials: a process improvement approach - PMC (nih.gov)
AMC#2 - Mayo Clinic Transforming the Activation of Clinical Trials - PMC (nih.gov)
AMC#3 – NCI Designated Cancer Centers https://ascopubs.org/doi/pdf/10.1200/OP.19.00325