

# **REDEFINING CLINICAL TRIAL START UP THROUGH CONTINUOUS IMPROVEMENT**

# Background

Clinical trial start up is a multifaceted process that occurs across a diversity of disciplines. Health systems must support caregivers by providing the appropriate tools, resources and training to promote timely execution of study activation. Eliminating bottlenecks in the activation process is critical to opening new studies quickly and efficiently and to providing patients the best possible treatment options. The objective of this project was to identify barriers within the current state activation process; then create new processes, tools, standards and trainings for an ideal state; and finally implement a future state workflow designed to reduce the total time to open a clinical trial.



# Metrics

- Set new activation target of 90 days (median) across all trial types (49% reduction from the baseline target of 175 days)
- Establish a committee of 15-20 multidisciplinary research staff
- **Develop portfolio of 10-15 sub-projects for risk management**
- Create diagram aligning sub-projects to stakeholder feedback



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### Methods

The project was completed in three phases:

- Utilize value stream mapping to identify current workflows and highlight waste, processing time and lead time.
- Replace current linear workflow with three new workflows: Cooperative Group, Industry Sponsored and Investigator Initiated clinical trials (60, 90 and 150 days, respectively)
- Collect data across research department using Crawford Slip, informal surveys, 1:1 meetings, team rounding, department meetings and a Kaizen event for new process roll out.

ne to Open a Clinical Trial: Sponsored Study Process F rocess Batch #2: 28 day PRMC Submissio Case CCC Disease Team Signoff ute Contract to Legal Clinical Study Order Specific alidation Training inalized Completed Negotiation Completed Pre-site Visit with Sponsor Protocol Received by Regulatory Coordinator Red Outline Indicates PI Engagement is Required for Task Completion

me to Open a Clinical Trial: IIT Study Process Flo Clinical Team \*CDA submission to Legal \*Legal review of CDA/Negotiation/ Approval Protocol Received by Regulatory Coordinator from PI OSRP/SPA Please reference CTMT for IND trials: https://iweb4.ccf.org/cancer/ IRB/PRMC IND ONLY Case CCC Disease Term Signoff Obtain cross Reference Letter Budget Negotiation Started Sponsor \*Consent to Sponsor Consent Approval Oncore Red Outline Indicates PI Engagement is Required for Task Completion <u>Note</u>: \*Asterisk Indicates "If Applicable

Time to Open a Clinical Trial: Coop Study Process Flow <u>NOTE</u>: LAPS grant reconciliation may add lead time Q1-Q2 each year Legend: Process Ownership Process Batch #2: 5 days Process Batch #3: 15 days CIRB Study Specific Worksheet Submission ocess Batch #1: 20 days ocess Batch #4: 10 days Protocol Received by Regulatory Coordinator Process Batch #5: 10 days CIRB Annual PI Worksheet Submission OSRP/SPA Activity # Received Clinical Calendar ser by Finance t Clinical Tear Task Log Feasibility Approval Study Specif Training Completed Red Outline Indicates PI Engagement is Required for Task Completion siv Indicates "if necessary





#### Outcomes

Results after the soft launch (Q3, 2019) showed a reduction to 178 days for the quarter, down from 210 days at baseline (Q1, 2019), a 15% decrease when comparing Q1 to Q3. Results after the full launch (Q4, 2019) showed a reduction to 150 days for the quarter, showing a near 29% reduction from baseline when comparing Q1 to Q4. The raw number of clinical trials that were activated in  $\leq$  90 days grew by 200% after full launch.



#### **Lessons Learned**

At the Cleveland Clinic Taussig Cancer Institute 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. Although the project is completed, we will continue to phase through the Plan Do Check Act cycle to evaluate gaps. Key components of the future strategy include:

- Establishing a dedicated start up team
- Developing a rewards and recognition system for meeting or exceeding targets Using clinical trial schemas to focus on gaps within disease groups Evaluating predictive tools for clinical trial accrual





