Category: Trial Start-up and Activation – Work In Progress

Improving Study Start-up Timelines: A Comprehensive, Multidisciplinary, Process-Improvement Initiative

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1. Background

In the current era of rapid medical advancements in the treatment of oncologic disorders, there is increasing emphasis on shortening clinical trial study start-up (SSU) timelines in order to remain competitive. Consequently, the University of Minnesota Masonic Cancer Center Clinical Trials Office (CTO), like other large academic CTOs, faced increasing pressure from key stakeholders to shorten SSU. Underlying drivers have been limited enrollment opportunities for multicenter early phase trials, timely publication of investigators' novel therapeutic approaches, and pressure to move new drugs to market in advance of our sponsors competitors (Sertkaya, Birkenbach, Berlind, & Eyraud, 2014). Unfortunately, our SSU phase remains > 300 days, nearly twice the national target.

Shortening the SSU timeline is a multifaceted and largely heterogeneous problem across CTO's (Abbott D, Califf R, Morrison BW, Chakraborty S. 2013). In addition, there is very little published research regarding specific barriers to SSU, preventing identification of umbrella solutions from literature sources alone. Therefore, our multidisciplinary team of clinical research coordinators (CRC), registered nurses (CRC-RN), regulatory specialists (RS), program managers (PM), and administrative leadership conducted an internal root cause analysis (RCA) focused on critical time points in the startup process. Several areas for improvement were identified. Presented here are recognized opportunities for change, critical timepoints, target timelines, collaborative process improvement strategies, and our evaluation metrics.

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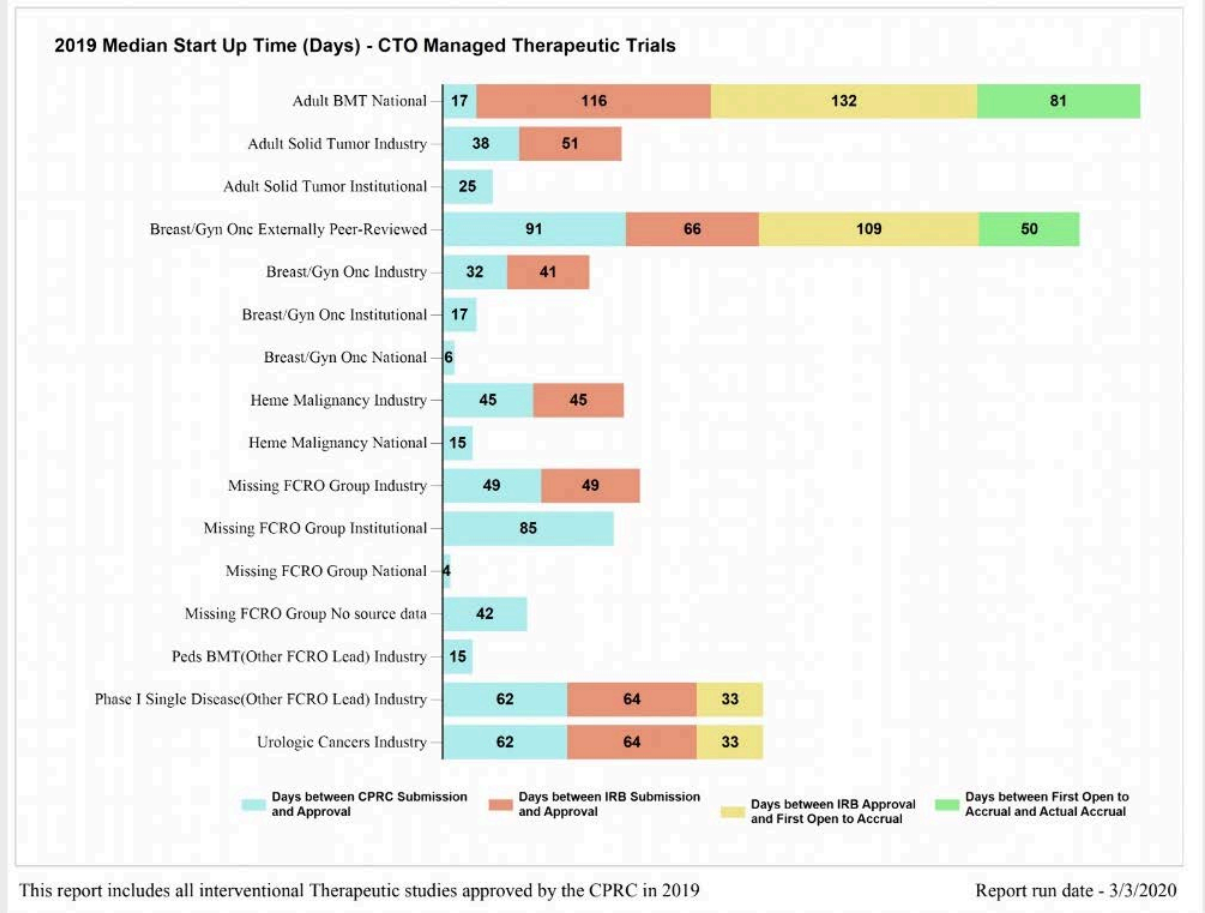

2. Goals

The primary objective of this quality improvement (QI) initiative was to improve SSU for complex investigator initiated clinical trials to < 180 days, and sponsor initiated or lower complexity trials to < 150 days. To achieve this, our multidisciplinary CTO team developed target timelines for each segment of the trial startup phase of the project lifecycle.

3. Solutions and Methods

We discovered several barriers to efficient study activation. Once identified, focus groups were created to set goals and implement QI initiatives targeting each barrier. Groups consisted of collaborators from a wide cross section of our CTO; allowing team members to provide expertise based on their unique practice ontology and experiential knowledge base. Projects identified as having the greatest potential impact on SSU are outlined here.

- Enhanced collaboration to define the breadth of trial complexity early in the SSU process
- Identification of common barriers leading to prolonged hold times
- Optimization of site initiation visits (SIV) schedules
- Improved workflow to develop multi-linear approaches, split executions, and parallel conduction of SSU processes

- Enhanced investigator education regarding available resources, facilities and infrastructure for project development
- Standardized workflows and defined SSU document checklists
- Identification of minimally required sponsor documents critical to advance projects through SSU steps

4. Outcomes

Preliminary outcomes will be presented at the AACI CRI meeting in July, 2020

5. Lessons Learned

Collaboration, real-time communication, transparency, and standardized practices were fundamental to our collective improvement in SSU timelines, ultimately leading to the consideration of advanced technology based platforms for real-time communication between clinical staff and within our community of research staff. Furthermore, establishment of an agreed upon SSU timeline was a pivotal milestone in our progress towards shortening SSU. Finally, this extensive CTO-wide initiative also heightened our regard for transparency as we sought to align our shared paths.