Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Fast-Tracking Cancer Research: Optimizing Study Startup for Accelerated Trial Activation at UFHCC

K. Calbart, E. Monari, A. Kukulka, A. Anderson, N. McGrew, A. Ivey, P. Crispen, T. George, C. Cline

University of Florida Health Cancer Center

1. Background

Timely clinical trial activation is crucial for advancing cancer research and providing access to new therapies. Operational inefficiencies have led to activation times exceeding our 90-day target. These delays were caused by fragmented workflows, redundant processes, and slow regulatory approvals and contracting. In response, University of Florida Health Cancer Center (UFHCC) launched a metric-driven initiative to optimize study startup and enhance collaboration by implementing project management techniques.

2. Goals

- Reduce study activation timeline to below 90 days
- Employ strategies to track progress, identify roadblocks, and facilitate faster resolution of delays
- Strengthen collaboration between regulatory, financial, and clinical teams.

3. Solutions and Methods

To identify barriers to activation, the startup process was divided into 5 subprocesses based on OnCore Status: NEW to Protocol Review Monitoring Committee (PRMC) Submission, PRMC Submission to Approval, PRMC Approval to Insitutional Review Board (IRB) Submission, IRB Submission to Approval, and IRB Approval to Open to Accrual. Metrics were collected for 2022 and 2023, consistently revealing extended delays in New to PRMC Submission and PRMC Approval to IRB Submission. Based on this data, we focused on these two development periods by implementing the strategies described below:

- A protocol development prioritization system was introduced to inform the management of multiple trials and reduce multitasking-related errors
- Startup staff were trained to draft billing grids for the centralized research compliance team, reducing review time. A tiered review system ensures accuracy prior to submitting for central review. With rare exception, UFHCC policy states that trial amendments requiring budget changes are deprioritized until after initial activation.
- IRB submission was aligned with PRMC approval for industry-sponsored trials, rather than waiting on contract execution. Historical data confirmed this as a low-risk, high-impact change.
- Additionally, a structured project management-inspired process was developed. Each startup team member is assigned as the project manager for a trial prior to activation and they are primarily responsible for meeting prescribed deadlines. Each trial is assigned clear target dates for subprocess completion along with escalation triggers via a tracking tool. Weekly meetings ensure real-time tracking, while biweekly meetings with institutional committees improve collaboration and reduced bottlenecks.

4. Outcomes

Preliminary results indicate that overall activation time for interventional trials has decreased from 106 days in 2022 to 96 days in 2024. As of mid-February, average activation for 2025 is 84 days.

We hope that these improvements will enhance patient access to trials and strengthen sponsor relationships. Furthermore, these process improvements will reinforce UFHCC's commitment to

operational excellence. By integrating established project management tools, prioritization frameworks, and parallel processing, we have established a more scalable and efficient startup model, supporting the institution's long-term research objectives.

5. Learned and Future Directions

Key lessons from this initiative include the importance of proactive tracking, cross-functional communication, and adaptive regulatory strategies. Improved communication between PAC teams, financial analysts, and regulatory bodies has enhanced responsiveness, while real-time tracking allows earlier detection of delays for timely interventions. A centralized MCA library is in development to further expedite that phase of startup by reducing redundant analyses. Moving forward, we plan to turn toward amendment processing to complete a similar process analysis and improvement plan.