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

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BACKGROUND

Efficient clinical trial activation is critical for advancing cancer research and providing access to novel therapies. Operational inefficiencies have caused activation timelines to exceed our target of 90 days. These delays stemmed from fragmented workflows, repetitive processes, and sluggish regulatory approvals and contracting. To address this, UFHCC launched a performance-driven initiative to streamline study startup and enhance team collaboration by applying project management principles.

Goals:

1. Reduce study activation timeline to less than 90 days
2. Implement strategies to track progress, identify obstacles, and expedite the resolution of delays
3. Foster stronger collaboration among regulatory, financial, and clinical teams

SOLUTIONS

To pinpoint activation barriers, the startup process was divided into five stages, based on OnCore Status:

1. NEW to PRMC Submission
2. PRMC Submission to Approval
3. PRMC Approval to IRB Submission
4. IRB Submission to Approval
5. IRB Approval to Open to Accrual

METHODS

Data collected from 2022 and 2023 highlighted significant delays in the New to PRMC Submission and PRMC Approval to IRB Submission phases. In response, we focused on these two stages by implementing the following strategies:

- A protocol development prioritization system was introduced to improve trial management and minimize multitasking errors.
- Startup staff were trained to draft billing grids for centralized research compliance review, which significantly reduced review times. A tiered review system was established to ensure accuracy before submission for final review. UFHCC policy prioritizes initial activation over trial amendments requiring budget changes.
- IRB submissions were aligned with PRMC approval for industry-sponsored trials, instead of waiting for contract execution, based on historical data indicating minimal risk and high impact.
- A structured project management-inspired framework was introduced. Each startup team member is designated as the project manager for a trial prior to activation and is responsible for ensuring deadlines are met. Clear target dates were set for each subprocess with escalation triggers monitored via a tracking tool. Weekly meetings enabled real-time tracking, and biweekly meetings with institutional committees helped reduce bottlenecks and improve collaboration.

RESULTS

Initial results show that the overall activation time for interventional trials has decreased from 106 days in 2022 to 96 days in 2024. As of mid-February 2025, the average activation time was 84 days.
Improvements are expected to increase patient access to trials and strengthen relationships with sponsors. Additionally, these process enhancements reinforce UFHCC's commitment to operational excellence. By integrating project management tools, prioritization systems, and parallel processing, we have created a more efficient and scalable startup model that supports long-term research goals.

Future Directions

- Key takeaways from this initiative highlight the importance of proactive tracking, cross-functional communication, and flexible regulatory approaches.
- Enhanced communication between PAC teams, financial analysts, and regulatory bodies has improved responsiveness, while real-time tracking facilitates the early identification of delays and timely interventions.
- A centralized MCA library is in development to further streamline the startup process by reducing redundant analyses. Moving forward, we plan to apply similar process analysis and improvement techniques to amendment processing.

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