Category: Trial Start-up, Activation, Regulatory, and Protocol Development – Work in progress

New Study Activation: A Centralized, Desegregated Model (i.e., Getting our Ducks in a Row)

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1. Background

In alignment with most NCI-Designated Comprehensive Cancer Centers, the imperative for rapid study activation has intensified at Fox Chase Cancer Center (FCCC). Beyond the essential requirements of the Cancer Center Support Grant (CCSG), financial considerations and recruitment goals underscore the need to expedite the study activation process.

At FCCC, siloed workflows, scattered interdepartmental communication, and increasing regulatory complexity had compounded the challenge, leading to prolonged activation timelines, a relatively substantial number of abandoned studies, and a subsequent lack of robust accrual.

2. Goals

We defined goals for an improved process, including:

- Centralize start-up across Disease Sites
- Provide transparency for key stakeholders, for new protocols and amendments
- Build standardization and communication across functional areas
- Shorten timelines

3. Solutions and Methods

We developed the Study Activation Unit (SAU), utilizing a hybrid model to combine centralized coordination with specialized expertise within individual areas. The SAU serves as the nucleus for this approach, facilitating seamless collaboration while maintaining rigorous oversight.

Key features of the hybrid model include:

- A Centralized Core: All new studies flow through the SAU, ensuring consistent processing and communication
- Area-Specific Expertise: Within each respective area (Clinical Operations, Regulatory, Feasibility/Scientific Review, Institutional Review Board (IRB), Quality Assurance, Contracts/Budgets), designated experts contribute their expertise
- Holistic Oversight: The SAU oversees all aspects of the activation pipeline, providing authoritative guidance, accountability, and key CCSG-required metrics

The SAU has implemented an efficient study activation process, emphasizing collaboration and adherence to critical parameters. Key components include:

- Microsoft Teams Page: A centralized startup checklist allows stakeholders to gather and confirm required documentation before initial submission (shortening time between site selection and feasibility review)
- REDCap: A required protocol submission intake form captures relevant CCSG and OnCore submission information - after the principal investigator (PI) completes this form, the SAU is responsible for vetting the information and ensuring the submitting Disease Site has met all criteria required for submission (reducing the back-and-forth previously experienced during study entry)

- OnCore Clinical Trial Management System (CTMS): Customized task lists updated in real-time by study teams (keeping teams on task with expected/required dates for each activation step)
- Study Statusboard: Integrated using information directly from both OnCore and electronic IRB systems (creating transparency across all areas)
- Microsoft Projects: Documenting milestones, assignments, and follow-up, and allows SAU to relay in real-time any specific tasks, however incremental, that each given department must complete (creating accountability)

The above systems are utilized in aggregate to provide real-time activation pipeline reporting to all stakeholders, allowing flexible metric retrieval.

4. Outcomes

While the formal establishment of the SAU occurred in early 2023, the groundwork began in calendar year (CY) 2022. Due to these efforts, FCCC has experienced a substantial reduction in the median time to activation for treatment trials:

- 263 days in CY2021
- 132 days in CY2022
- 84 days in CY2023

5. Lessons Learned and Future Directions

Complexities faced have resulted from fully aligning the four concurrent Activation streams: committee submission, clinical operations, budgets, and most notably, contracts. Key areas of improvement currently targeted include prioritization of Study Initiation Visits, and Master Agreements and Master Rate Card development. Future SAU efforts will focus on extending the activation processes to amendments.