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

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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.

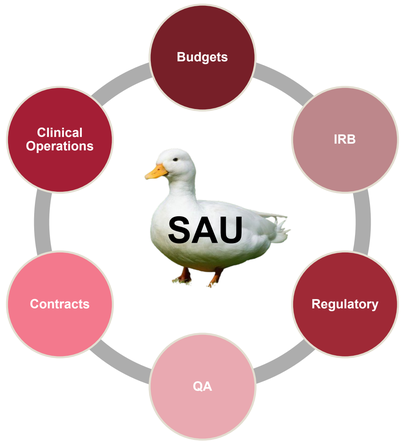
At FCCC siloed workflows, scattered interdepartmental communication, and increasing regulatory complexity had compounded the challenge, leading to prolonged activation timelines, a relatively substantial number of abandoned studies, and a subsequent lack of robust accrual.

GOALS

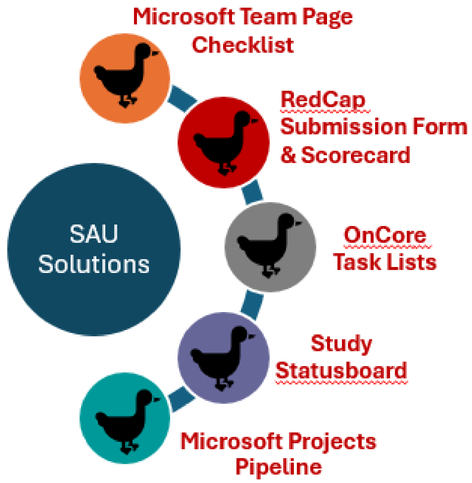
- Centralize Start-up Across Disease Sites
- Transparency for Key Stakeholders
- Shorten Timelines

METHODS AND SOLUTIONS

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.



- ***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, IRB, QA, Contracts/Budgets), designated representatives contribute expertise
- ***Holistic Oversight:*** The SAU oversees all aspects of the activation pipeline across disease sites, providing authoritative guidance, accountability, and key CCSG-required metrics



A **centralized startup checklist in MS Teams** allows stakeholders to gather and confirm required documentation before initial submission (shortening time between site selection and feasibility review)

A **protocol submission intake form** captures relevant CCSG and OnCore information - after completion, the SAU vets the information, ensuring the submitting Disease Site has met all required criteria (reducing back-and-forth during study entry)

Customized task lists are updated in real-time by study teams (keeping teams on task with expected dates for each activation step)

The **Statusboard** integrated information directly from both OnCore and eIRB systems (creating transparency across all areas)

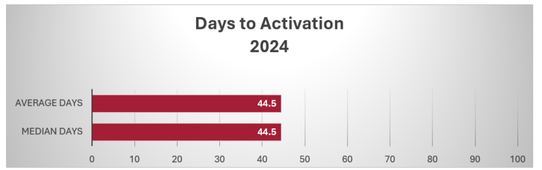
Documenting milestones, assignments, and follow-up in **Microsoft Projects** allows SAU to relay concurrently any specific tasks, that each given department must complete (creating accountability)

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

OUTCOME

FCCC has experienced a substantial reduction in the median time to activation for treatment trials:

- 267 days in CY2021
- 133 days in CY2022
- 85 days in CY2023



LESSONS LEARNED

By fully aligning the four concurrent Activation streams (committee submission, clinical operations, budgets, and most notably, contracts) we have improved workflows. Key areas of future improvements include prioritization of Study Initiation Visits, and Master Agreements/Rate Card development.

FUTURE DIRECTIONS

Extend the activation processes to amendments.