Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Implementation of a Centralized Clinical Trial Activation Unit Leads to Significant Reduction in Time to Activation at an NCI-Designated Cancer Center

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1. Background
Clinical trials afford cancer patients access to potentially life-saving innovative therapies and may inform treatment options for future patients. Rapid trial activation is foundational in helping address time-sensitive research questions in cancer populations with aggressive, refractory or rare diseases. Efficient activation maximizes enrollment opportunities, optimizes resource management, and enhances sponsor relationships. Streamlined activation processes increase trial availability, ultimately creating a more robust portfolio of cutting-edge treatment options for our diverse patient population.

2. Goals
Our primary objective was to reduce therapeutic trials median time to activation (TTA) to 120 days over the course of one year through process optimization and enhanced cross-functional collaboration. Our secondary goals included increasing the number of activated trials, especially federally funded trials and investigator-initiated trials (IIT).

3. Solutions and Methods
The UC San Diego Health Moores Cancer Center clinical trials organization was comprehensive restructured, creating a centralized activation unit which was launched in April 2024 staffed by dedicated activation specialists, alongside an embedded IIT unit. A TTA task force, which included key stakeholders, met weekly, enhancing collaboration between the Clinical Trials Office, coverage analysts, IRB, contracting, and biomedical informatics. The task force defined goals and metrics, tracked progress weekly using a new project management software, and employed an interactive approach to develop solutions, standardizing activation workflows and proactively addressing barriers.

4. Outcomes
Implementation of this initiative resulted in significant improvements in trial activation metrics, and numbers of trials activated. The median TTA decreased from 400 days in 2021, 408 days in 2022, 267 days in 2023, to 122 days in 2024 for studies entering the new activation unit. Profound reductions were achieved in key activation components, including IRB approval time, coverage analysis completion, budget negotiations, and contract execution. The number of activated therapeutic trials increased from 63 in 2021, 45 in 2022, to 83 in 2023 and to 104 in 2024. Enhanced operational efficiency led to more predictable activation timelines and improved sponsor relationships.

5. Lessons Learned and Future Directions
Centralized and dedicated resources are essential for efficient trial activation. Regular cross-functional meetings facilitate rapid problem-solving and process improvement. Moving forward, we plan to further refine processes to achieve a 90-day median TTA goal, implement additional technology solutions, develop predictive metrics to identify potential delays early in the activation process, and expand the centralized model to other aspects of clinical trial operations. These improvements provide a foundation for sustained excellence in clinical trial operations and expand access to innovative cancer therapies to patients.

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