From 216 to 88 Days: Optimizing Clinical Trial Activation Through an Operations Driven Approach

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Background

Start up timelines remain a significant operational challenge for many academic medical centers, particularly in oncology, where regulatory, departmental review processes, and sponsor requirements can be cumbersome, leading to delayed patient access to innovative trials.

At our institution, clinical trial activation was identified as a key opportunity area for improvement. To address this, we implemented a structured, operations-driven initiative to reduce activation timelines, specifically for industry-sponsored and National Clinical Trials Network (NCTN) oncology trials.

Objective

To reduce overall study activation timelines for industry-sponsored and NCTN trials and improve the study activation workflow across institutional departments.

Methods

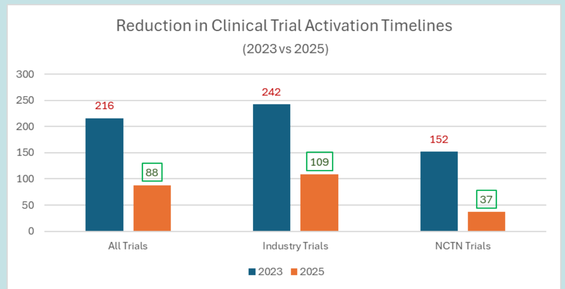
Institutional Support: Clinical Trial Activation Task Force
- Membership: Office of the Vice Chancellor for Research (OVCR), Cancer Center Clinical Trials Office (CTO), Clinical Research Finance Office (CRFO), Institutional Review Board (IRB), and Office of Sponsored Program (OSP)
- Charge: Review activation metrics, identify bottlenecks, and monitor implementation of revised processes.
- Monthly meetings

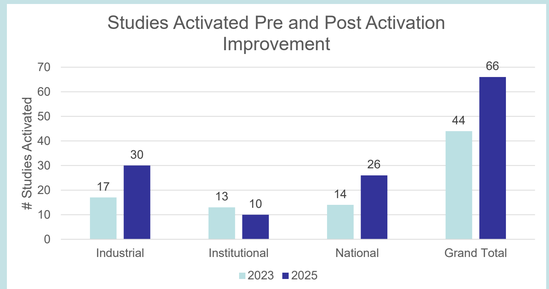
Clinical Trials Office Process Improvement Plan
- Membership: CTO management team and study activation specialists
- CTO Management Retreat to brainstorm potential areas for improvement
- Created Weekly Study Start Up Meeting to review all studies in activation and implement process improvements
- Created a checklist for studies to be greenlight for PRC submission and aligned submission volume with the PRCs review capacity.
- Updated SOPs to support streamlined review and regulatory submission process

Increased Institutional Commitment and Reorganization
- Centralized study activation activities into Study Activation Unit
- Created dedicated Study Activation Manager Position
- Increased total study activation staff from 2 FTE to 4 FTE
- Hired protocol developer to assist with IIT development

Results

Changes made to activation process:
- Removed departmental approval requirement as part of IRB review
- Expedited local IRB acknowledgement to submit to external IRB
- Coordinated institutional handoffs
- Approval of full protocol in disease team and approval of site start up fees prior to Feasibility Meeting
- Consent forms must be finalized prior to PRC submission
- Medical Coverage Analysis is submitted to CRFO prior to IRB submission
- Weekly Study Start up meeting with CTO Managers and Study Activation Team
- **Focus on Front-End Activation Readiness**
- Created comprehensive Site Information Packet with key SOPs, Site Profile, Site Administrative Fees, and Sponsor Questionnaire
- Streamlined investigator and staff HRS, GCP, MLs and CVs sponsor sharing
- Created a master site contact form
- Require activating on the protocol version sponsor initially provides, protocol amendments submitted after study activation





- **Median activation: 216 days to 88 days, an overall reduction of 59%**
- **Increased number of studies activated per year from 44 to 66 (50% increase)**
- Strengthened cross-departmental communication
- Improved transparency of startup metrics
- Reinforced shared institutional responsibility to have trials available as soon as possible to our patients.
- Minimized duplicative administrative effort

Conclusions

Institutional support, workflow redesign, and proactive standardization provide a replicable framework for institutions aiming to improve clinical trial activation. Future efforts will focus on sustaining the progress made, fine tuning our processes for continued improvement, and harnessing sponsor-institution relationships for streamlined workflows.

Acknowledgements

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