

*Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Work in progress*

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

C. Garza, D. Kitterman

*University of Illinois Cancer Center*

### **1. Background**

Extended startup timelines remain an 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.

### **2. Goals**

To reduce activation timelines for both industry-sponsored and National Clinical Trials Network (NCTN) trials by implementing a structured, operations-driven initiative focused on institutional alignment, workflow redesign, and front-end activation readiness.

### **3. Solutions and Methods**

A Clinical Trial Activation Task Force was established, led by the Office of the Vice Chancellor for Research (OVCR) and including leadership from the Cancer Center Clinical Trials Office (CTO), Clinical Research Finance Office (CRFO), Institutional Review Board (IRB), and Office of Sponsored Program (OSP). The task force met monthly to review activation metrics, identify bottlenecks, and monitor process improvements, with executive engagement ensuring shared accountability.

The CTO completed a comprehensive process-mapping assessment and identified drivers for improvement. We initiated weekly start up meetings with CTO managers and the study activation team to review, prioritize and troubleshoot potential delays. Workflows were optimized to ensure consent forms, beacon plans, study calendar builds and Medical Coverage Analysis (MCA) were aligned with Protocol Review Committee (PRC) and IRB submissions. These workflows were redesigned to support parallel processing where feasible. These internal changes increased transparency in start-up delays and allowed for proactive intervention when potential barriers were identified.

Front-end activation readiness was also addressed at the CTO level. Standard operating procedures and site documents were revised to front-load complete and standardized information, reduce duplication, and proactively address common sources of start-up delays, such as amendments during start up. This both minimizes iterative queries and ensures site readiness for sponsor greenlight.

### **4. Outcomes**

Following implementation, median activation timelines decreased from 242 days in 2023 to 109 days in 2025 for industry trials and from 152 days (2023) to 37 days (2025) for NCTN trials. Across all trials, our median activation has gone from 216 days (2023) to 88 days (2025), representing an overall reduction of 59 percent. Beyond measurable time savings, these interventions strengthened cross-departmental communication, improved transparency of startup metrics, and reinforced shared institutional responsibility.

### **5. Lessons Learned and Future Directions:**

Institutional support, workflow redesign, and proactive standardization are critical to reducing trial start-up timelines. These strategies provide a replicable framework for other institutions aiming to improve

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clinical trial activation efficiency and strengthen cross-departmental collaboration. Future efforts will focus on sustaining the progress made and fine tuning our processes for continued improvement.