Category: Clinical Trial Operations (Trial Startup, Regulatory, Finance, Data Management, IITs) – Completed Project

Clinical Trial Project Managers: the Air Traffic Controllers of Study Activation

S. Raboin[1], E. Stanley[2], A. Gateman[1]

Yale Cancer Center, Yale School of Medicine[1]; Huron Consulting Group[2]

1. Background

Clinical trial activation delays are frequently driven by misalignment due to fragmented ownership of start-up activities and inconsistent workflows. Working with Huron Consulting Group, Yale Cancer Center (YCC) identified the need for a distinct role focused on coordinating and driving activation across functions for new trials and amendments. In response, the Clinical Trial Project Manager (CTPM) role was implemented to streamline operations by centralizing coordination, aligning teams, and proactively resolving issues.

2. Goals

The primary goal was to reduce activation timelines by embedding CTPMs as a discrete operational role. Additional goals included:

- Standardizing activation and amendment workflows
- Strengthening adaptability to manage shifting workloads and staffing changes
- Improving visibility into study status and blockers
- Reducing administrative burden on study teams

3. Solutions and Methods

YCC implemented a CTPM model in which each Clinical Research Team (CRT) is assigned a CTPM responsible for end-to-end oversight of activation. Unlike traditional activation coordinators embedded within functional teams, CTPMs operate as an independent business function accountable for study intake, confidentiality agreement processing, feasibility coordination, CRT review, and milestone management. CTPMs also own and manage the amendment queue, ensuring amendments follow the same standardized workflows and prioritization logic as initial activation.

To support the CTPMs, YCC developed toolkits designed to standardize activation activities. These toolkits included process maps, checklists, and dashboard templates. The toolkits enabled consistent execution across CRTs and ensured that CTPMs had the resources needed to drive efficiency and accountability throughout the trial lifecycle.

CTPMs played a pivotal role in facilitating stakeholder meetings and overseeing the centralized REDCap metric tracker. These meetings brought together representatives from clinical, regulatory, contracting, and finance teams to review progress, address bottlenecks, and ensure alignment on study priorities. The centralized tracker provided a transparent and standardized overview of activation milestones, current statuses, and upcoming deliverables for all studies in the pipeline.

4. Outcomes

Following implementation, YCC observed measurable improvements in activation efficiency, including a 51 percent reduction in time to activation timelines between 2025 and the 2022 pre-CPTM model timelines. Standardized communication, coordination, and prioritization directed by the CTPMs improved predictability for regulatory, contracting, and budgeting, while reducing administrative burden

on clinical and regulatory teams. Centralized reporting reduced meetings and improved visibility into bottlenecks.

5. Lessons Learned and Future Directions

Successful implementation of the CTPM model hinged on recruiting candidates with organizational skills, relevant research experience, and the communication skills and assertiveness to coordinate multidisciplinary teams. These qualities were essential for ensuring that CTPMs could navigate complex workflows, coordinate among diverse stakeholders and escalate bottlenecks during the activation process. Key to the success was a separate reporting structure with a direct line to the YCC CTO Administrative Director, which helped to reinforce adherence to a unified activation process and ensure action on escalated items.

Key to success were change management strategies, including stakeholder engagement and transparent communication, and detailed written workflows to ensure standardization and escalation pathways. Early and ongoing involvement functional teams with the strategies and the workflows helped build buy-in for the new model and ensure alignment.

Future work will focus on enhanced analytics, with plans to leverage data from the tracker and other workflow tools into Business Intelligence (BI) dashboards to further optimize activation timelines, proactively identify bottlenecks, and support data-driven decision-making.