

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

## **Accelerating Activation by Overcoming Roadblocks**

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### **1. Background**

Clinical trial activation timelines for industry-sponsored oncology trials at Yale Cancer Center (YCC) are heavily influenced by business office processes, particularly Medicare Coverage Analysis (MCA), budget development and negotiation, and financial alignment with contracting and regulatory workflows. While budgeting is frequently cited as a critical path activity, delays often stem from interdependencies between MCA determinations, sponsor budget negotiations, contract terms, and informed consent language, resulting in downstream rework and extended activation timelines.

Oncology trials present additional challenges due to complex standard-of-care determinations, MCA requirements, evolving protocol amendments during start-up and frequent sponsor-driven budget revisions. Delays in sponsor budget negotiations, misalignment between informed consent forms, contract terms and final budgets, can create downstream bottlenecks that delay regulatory submission readiness and overall activation.

Recognizing that many activation delays are impacted by business office workflows, the YCC Business Office partnered with its start-up vendor, WCG, to analyze key financial and operational causes of delay and implement targeted process improvements focused on MCA completion, budget turnaround times, and coordination across activation sequences.

### **2. Goals**

The primary goal was to improve overall time to activation for industry-sponsored oncology trials by:

- Identifying bottlenecks, particularly within MCA and budget workflows
- Reducing budget negotiation timelines
- Improving alignment between MCA determinations, sponsor budgets, contracts, and informed consent documents
- Establishing proactive escalation pathways to prevent downstream activation delays

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

YCC and WCG maintain detailed start-up metrics, including milestone tracking, duration between start/stop points, and categorized reasons for delay. A focused analysis of metrics identified recurrent delays in:

- MCA completion
- Sponsor/Clinical Research Organization (CRO) budget negotiation turnaround times
- Misalignment across documents

To address these gaps, YCC implemented a data-driven approach emphasizing early alignment, parallel processing, and defined accountability. Key interventions included:

- Weekly joint budget review meetings between the YCC and WCG to proactively monitor trials nearing timeline targets, identify outliers, and resolve issues in real time

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- Defined escalation triggers and pathways, including direct sponsor engagement, Principal Investigator (PI) outreach to sponsor contacts, and leveraging established sponsor relationships across both YCC and WCG
- A pre-activation financial congruency review to ensure alignment across the executable contract, final budget, approved MCA, and informed consent prior to activation—reducing post-activation amendments and minimizing downstream Clinical Trial Management Software (CTMS) build errors

#### **4. Outcomes**

Implementation of these strategies resulted in measurable improvements in Business Office performance metrics, including:

- Reduction in median budget negotiation timelines
- Reduction in rework related to MCA/budget/contract misalignment
- Improved predictability in financial milestone completion

These improvements contributed to an overall reduction in time to activation for industry-sponsored oncology trials.

- FY2023 Median days to activation 238; activating 75 trials
- FY2024 Median days to activation 183; activating 97 trials
- FY2025 Median days to activation 111; activating 101 trials

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

This initiative demonstrated that clearly defined early escalation triggers are critical to preventing prolonged sponsor/CRO negotiation delays. Proactive alignment of MCA determinations, budgets, and contract language reduces rework and minimizes activation bottlenecks, while structured financial review meetings improve transparency and enables earlier intervention.

Moving forward, YCC will implement sponsor-specific performance dashboards to identify recurring delays and support more proactive, data-driven activation strategies.