

Accelerating Activation by Overcoming Roadblocks

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OPERATIONAL CHALLENGE

Clinical trial activation timelines for industry-sponsored oncology studies at Yale Cancer Center are significantly impacted by business office workflows, including Medicare Coverage Analysis (MCA), budget negotiation, and alignment with contracting and regulatory processes. Delays often result from dependencies between MCA determinations, sponsor budget revisions, contract terms, and informed consent language, creating downstream rework and extended activation timelines.

Oncology trials present additional complexity due to standard-of-care determinations, protocol amendments during start-up, and frequent sponsor-driven budget changes. To address these challenges, the YCC Business Office partnered with WCG to evaluate operational and financial causes of delay and implement targeted process improvements focused on MCA completion, budget turnaround time, and cross-functional coordination.

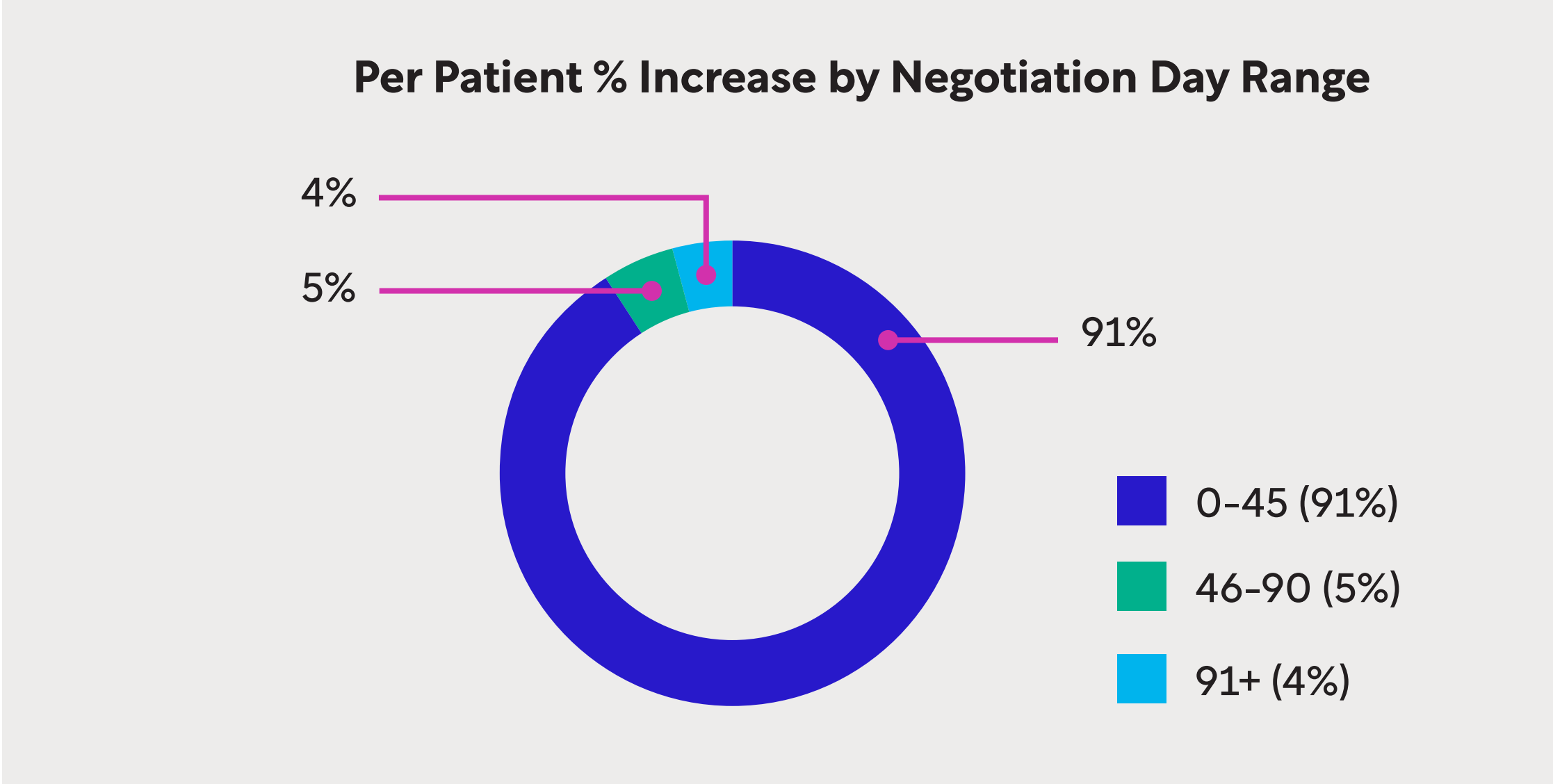
GOALS

Improve activation timelines for industry-sponsored oncology trials by:

- Identifying workflow bottlenecks.
- Reducing MCA and budget negotiation delays.
- Improving alignment across budgets, contracts, and informed consent documents.
- Establishing proactive escalation pathways to prevent downstream delays.

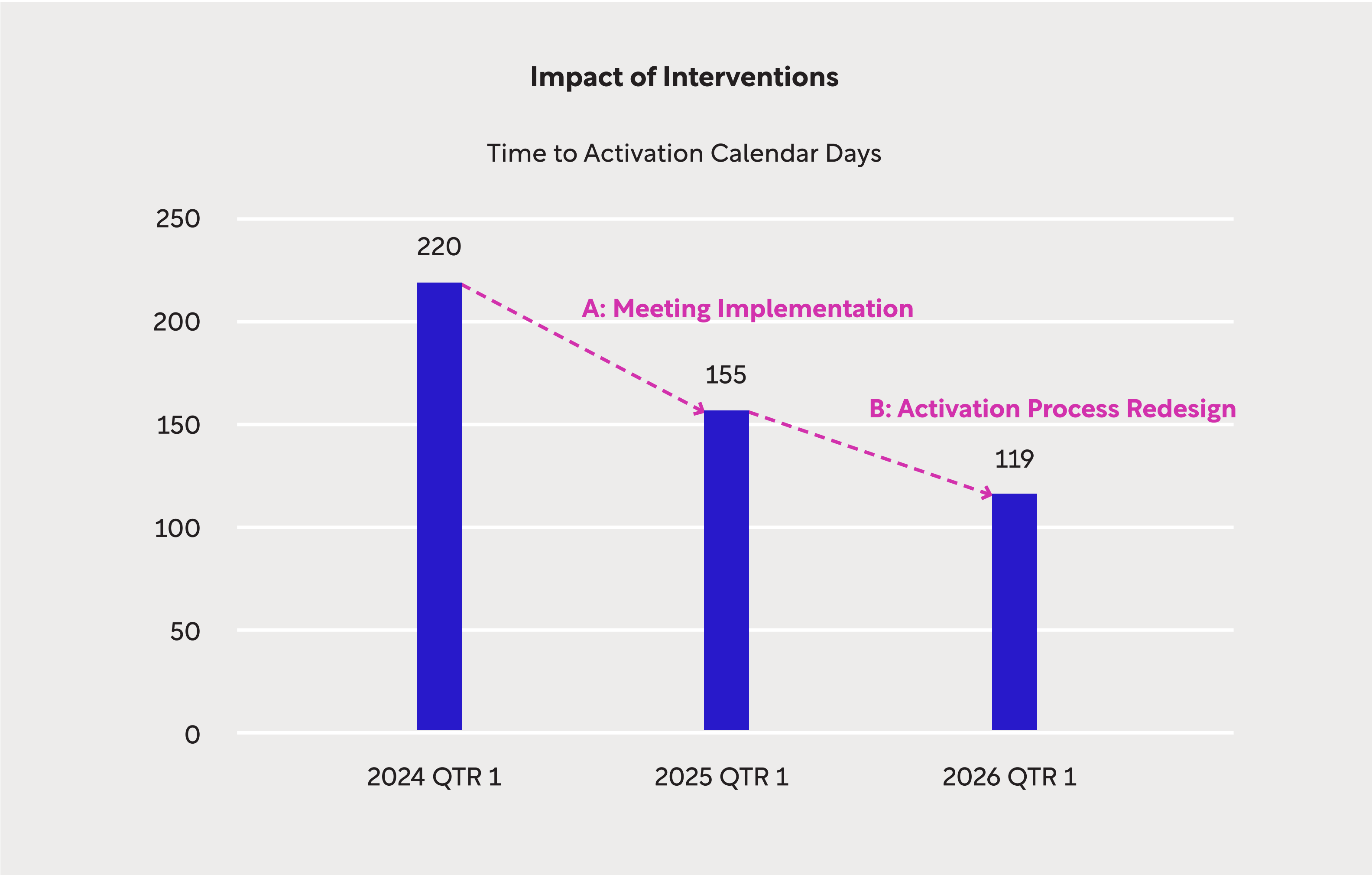
NEGOTIATION DURATION ON BUDGET OUTCOMES

Analysis of active negotiation timelines demonstrated that 91% of the most meaningful per-patient fee increases were achieved within the first 45 days of negotiation. Beyond day 45, additional negotiation rounds resulted in minimal financial impact, indicating limited return on prolonged negotiations.



OUTCOMES

Implemented a data-driven approach focused on early alignment, parallel processing, and accountability.



A - Meeting Implementation

Established weekly YCC/WCG budget review meetings to monitor timelines, identify outliers, and resolve issues proactively. Created defined escalation pathways involving sponsors, PIs, and YCC/WCG leadership.

B - Activation Process Redesign

Repositioned financial build activities to occur before full contract execution reduced bottlenecks and improved activation turnaround times. Also, adding a pre-activation financial congruency review to align contracts, budgets, MCA, and informed consent documents prior to activation reduced downstream amendments and CTMS build errors.