OMNITEK CONSULTING

Breaking the Site Activation Bottleneck

WHITE PAPER

Why Startup Still Takes Five to Six Months, and What Actually Shortens It

Abstract

Site identification to activation has taken five to six months on average for over a decade, a timeline that has not meaningfully improved even as trial technology has advanced almost everywhere else in the clinical development process. Eleven percent of selected sites never activate at all, most often derailed by budget and contract negotiation rather than by clinical capability or patient access. The cost of that delay is real and quantifiable: recent Tufts Center for the Study of Drug Development analysis puts the direct operating cost of a day of trial delay at roughly $40,000, rising above $55,000 for a Phase III study, before accounting for the separate, larger cost of delayed access to revenue. Contracting and budget negotiation, not IRB review, remain the single biggest source of cycle time and unpredictability in the activation process for most sponsors, a pattern that holds across therapeutic areas and site types. This white paper applies established connected trial systems and process integration best practices to site activation specifically, laying out how sponsors and CROs can move contracting, IRB review, and budget negotiation into a genuinely parallel, connected process instead of the serial handoff chain that produces most of the delay.

A Timeline That Has Not Moved in a Decade

Site identification to activation has averaged five to six months for more than ten years, a figure that has held remarkably steady even as electronic data capture, remote monitoring, and centralized statistical review have all measurably accelerated other parts of clinical trial conduct. Eleven percent of sites selected for a study never actually activate, and the leading cause is not a clinical or patient-access problem. It is a budgeting and contracting problem that derails the site before it ever reaches its first patient.[i]

The cost of that stagnation is not abstract. Tufts CSDD's most recent day-of-delay analysis puts direct trial operating costs at roughly $40,000 per day on average, rising to $55,716 per day for a Phase III study, a figure that revises earlier, widely repeated estimates sharply downward but still represents a real and continuous cost accumulating for every day a site sits unactivated.

Where the Delay Actually Concentrates

Contracting and budget negotiation, not IRB or ethics review, consistently show the longest cycle time and the highest variance across the site activation process. That finding holds across multiple industry benchmarking studies spanning nearly a decade, and it points to a specific structural problem: most activation processes still treat contract negotiation, budget agreement, and regulatory document collection as sequential steps handled by different functions with limited visibility into each other's progress.

IRB review timelines tell a related but separate story. A Duke Clinical Research Institute cohort study found central IRB review averaging 78 days compared to 165 days for local IRB review at the same sites, with total site start-up time averaging 199 days under a central IRB model versus 287 days under local review, a roughly 44% reduction in overall timeline attributable largely to that single structural change.[ii] The UK's RECOVERY trial demonstrated an even more extreme version of what parallel, standardized activation can achieve, enrolling its first patient just nine days after protocol finalization by running site activation, contracting, and ethics review in parallel against standardized templates rather than as a serial chain.

Applying Best Practices: Connecting Activation Instead of Chaining It

A foundational best practice in connected trial systems design, that a connected ecosystem only delivers value when its parts function together rather than as isolated handoffs, applies as directly to the people and process side of site activation as it does to system integration. Most activation delay is not caused by any single step taking too long. It is caused by steps that could run in parallel instead running one after another because no one owns the connections between them.

1. **Parallel-Track Design as the Default Activation Model.** Run contract negotiation, budget agreement, and regulatory document collection concurrently rather than sequentially wherever the site relationship allows it, rather than defaulting to a serial handoff chain because that is how the process has always run.
2. **Standardized Contract and Budget Templates Negotiated in Advance.** Reduce the negotiation surface at the site level by settling as much contract and budget language as possible at a master agreement or program level before individual site negotiations begin.

3. **A Single IRB Strategy Applied Wherever the Regulatory Environment Allows.** Default to central IRB review over local review where feasible, given the documented timeline advantage, reserving local review for the specific circumstances that genuinely require it.
4. **Real-Time Cross-Functional Visibility Into Activation Status.** Give every function involved in activation, contracts, regulatory, clinical operations, visibility into where each site actually stands, so a stalled step is visible and addressable rather than discovered weeks later at a status meeting.

None of this requires abandoning the diligence contract and budget negotiation genuinely require. It requires removing the artificial serialization that turns steps which could run concurrently into a chain of handoffs, each one waiting for the last.

What Parallel-Track Activation Buys, and Where It Gets Hard

Advantages

- **Meaningfully shorter time from site selection to first patient:** removing artificial serialization directly targets the cycle time that has resisted a decade of otherwise steady clinical trial technology improvement.
- **Fewer sites lost to activation entirely:** addressing contracting and budget friction directly targets the leading cause of the eleven percent of selected sites that never activate.
- **Reduced direct trial cost accumulation:** every day removed from the activation timeline offsets a real, quantifiable daily operating cost that compounds across every unactivated site.
- **A documented central IRB timeline advantage sponsors can act on directly:** the roughly 44% total start-up time reduction attributable to central IRB adoption is a specific, evidence-backed lever available without waiting on new technology.

Risks and Barriers

- **Parallel-track processes require genuine cross-functional coordination:** running contracting, budget, and regulatory workstreams concurrently only works if each function has visibility into what the others are doing and where dependencies actually exist.
- **Standardized templates meet real site-level resistance:** some sites and institutions have their own required contract language, and a template-first approach needs a defined negotiation path for those exceptions.
- **Central IRB adoption is not universally available or appropriate:** some sites, institutions, or regulatory environments require local IRB review regardless of the documented timeline advantage of central review.
- **Real-time visibility requires a shared system of record:** cross-functional status transparency depends on a tracking system every function actually updates, which is itself a change management effort.

Case in Point: The Site Portfolio Activated in Half the Time

A mid-size sponsor running a multi-region Phase II trial had historically activated sites through a serial process: regulatory document collection first, followed by contract negotiation, followed by budget finalization, with each step formally gated on completion of the previous one. Site activation for the sponsor's prior comparable trial had averaged just over five months, consistent with the broader industry pattern.

For the new trial, the sponsor restructured the process around three concurrent workstreams, regulatory document collection, contract negotiation, and budget discussion, launched simultaneously at site selection rather than sequentially, with a shared tracking dashboard giving each function visibility into the others' progress and any site-specific blockers. The sponsor also pre-negotiated standardized contract language at a program level with its most frequently used site network, reducing the individual negotiation surface for roughly a third of participating sites.

Average site activation time for the new trial came in just under ten weeks, less than half the sponsor's historical average, with the sites using pre-negotiated program-level contract language activating fastest of all. The sponsor's clinical operations team identified the shared visibility dashboard, more than any single process change, as the factor that let them catch and resolve stalled negotiations days rather than weeks after they stalled.

Recommendations for Clinical Operations and Site Contracting Leaders

1. **Redesign activation as parallel workstreams from the outset.** rather than a serial chain of gated handoffs between functions.
2. **Negotiate standardized contract and budget language at the program level.** before individual site negotiations begin, wherever a site network relationship allows it.
3. **Default to central IRB review wherever the regulatory environment permits.** given the documented timeline advantage over local review at comparable sites.
4. **Build shared, real-time visibility into activation status across every function involved.** so a stalled step is caught and addressed in days rather than discovered at a periodic status meeting.
5. **Track site non-activation rate and its root causes explicitly.** rather than treating a site that never activates as an isolated, unexplained loss rather than a signal about the process itself.
6. **Benchmark activation time against the industry's five-to-six-month baseline directly.** so improvement targets are measured against a documented, decade-stable reference point rather than an internal assumption.

Measuring Success: KPIs for Site Activation Performance

- **Median site identification-to-activation time:** tracked against the industry's documented five-to-six-month baseline as the primary measure of activation process performance.
- **Site non-activation rate:** the percentage of selected sites that never activate, tracked with root cause attribution rather than as an unexplained aggregate figure.
- **Contract and budget negotiation cycle time:** tracked separately from IRB review time, given its consistent status as the largest single source of activation delay.
- **Central versus local IRB timeline differential:** tracked at the program level to quantify the specific benefit a sponsor's own central IRB adoption is actually delivering.

Conclusion

A five-to-six-month activation timeline that has not moved meaningfully in a decade is not evidence that site activation cannot go faster. It is evidence that the serial handoff structure most sponsors still use has never been seriously redesigned, even as nearly every other part of clinical trial conduct has been rebuilt around parallel, connected workflows.

Applying disciplined best practices to site activation specifically, parallel-track workstreams, standardized program-level contracting, a central IRB default, and real-time cross-functional visibility, targets the specific structural cause of a delay that has cost the industry a documented, quantifiable amount for every day it persists.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.

For clinical operations and site contracting leaders looking to shorten activation timelines, OmniTek applies proven best practices to build a practical parallel-track activation model: standardized program-level contracting, a central IRB default, and shared real-time visibility across every function involved. Whether you are redesigning your activation process for an upcoming program or diagnosing why a current trial's sites are stalling before first patient in, OmniTek can help you turn a serial bottleneck into a connected, concurrent process.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.

McLean, VA | Serving clients nationwide
info@omnitekconsulting.com
omnitekconsulting.com

Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.

Endnotes

[i] Tufts Center for the Study of Drug Development, site activation and start-up benchmarking research, on average site identification-to-activation timelines and site non-activation rates, reported via Applied Clinical Trials, available at https://www.appliedclinicaltrialsonline.com/view/molasses-study-startup-efficiencies

[ii] ACRP, citing Duke Clinical Research Institute cohort study (Goyal et al.), on central versus local IRB review timelines and total site start-up time, available at https://acrpnet.org/2026/02/17/improving-study-start-up-efficiency-to-accelerate-the-clinical-trial-timeline