

# AI is no longer the bottleneck: Why clinical development must shift from innovation to execution

## A KEY QUESTION



How can clinical development shift from AI innovation to disciplined execution that truly compresses timelines?

## KEYWORDS

Clinical Trial Execution, Study Start-Up, Operational Intelligence, Clinical Data Interoperability, Sponsor–Site Burden Reduction



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Artificial intelligence (AI) is moving from the margins of healthcare development to mainstream. What began as a technology rich with promise but unclear in application, is quickly evolving into an essential part of modern trial design and delivery. Yet despite widespread interest and investment, the industry now needs to move beyond isolated AI pilots into consistent, reliable benefits executed at scale. The challenge is no longer whether AI belongs in clinical development; it is whether we are executing it well.

At the recent Fortrea Intelligent Technology (FIT) Summit (April 2026, Boston, MA), industry leaders converged on a shared conclusion: progress is now constrained not by the availability of technology, but by the ability to embed it into concrete workflows, governance models and operating practices.

AI has proved its potential. What remains unproven is how to move beyond experimentation, proofs of concept and disconnected solutions, and into sustained impact that accelerates trials, reduces burden and contributes to meaningful outcomes for patients, sites and sponsors alike.

The next era of clinical development will not be determined solely by innovation. It will be defined by strong technology execution in which intelligence is industrialized, scale is intentional and AI delivers value not occasionally, but predictably.

## Pilot purgatory

Over the past decade, clinical development has benefited from unprecedented advances in data science, AI and digital technologies. Yet these advances are at best incremental in impact, with trial timelines continuing to stretch, site and patient burden remaining high and the distance between breakthrough and bedside remaining stubbornly wide. The conclusion emerging from the FIT Summit in Boston in April 2026 was not that we need more technology, but that we must fundamentally change how we deploy it.

This is a moment of inflexion for the industry. Incremental optimization will no longer be enough. The challenge is not a lack of ideas, but rather the inability to consistently translate those ideas into a live, governed, operational reality.

Too often, innovation exists alongside the workflow rather than within it. As a result, promising tools stall in **“Pilot purgatory,”** disconnected from the people and processes they were designed to support.

The next phase of clinical development will be defined by organizations that can move beyond experimentation and industrialize innovation, embedding intelligence directly into how trials are designed, run and managed, rather than layering solutions on top of legacy processes.

## Time is the outcome that matters most

The life sciences industry, like many others, has traditionally framed transformation through the lens of cost. Efficiency programs are routinely justified by savings, productivity gains or reductions in operational overhead. However, there is a different and more consequential measure of success—time:

- Time from scientific discovery to real-world impact
- Time to first patient in
- Time to meaningful insight
- Time clinicians are able to spend with patients vs. spent on administration

These are not abstract metrics. They represent the lived experience of patients awaiting new therapies,

of sites operating under sustained capacity pressure and of clinical teams navigating ever-increasing complexity. In this context, time is not merely an operational variable, rather a human outcome. Every delay compounds burden, extends uncertainty and postpones benefit.

Reframing the challenge in these terms fundamentally changes the role of technology in clinical development. The purpose of intelligent systems is not primarily to reduce headcount or constrain budgets. Rather, it is to compress timelines responsibly—to remove friction from decision-making, eliminate avoidable delays and enable work to progress at the pace science now demands, without compromising quality or rigor.



As Fortrea’s CRO, Anshul Thakral, puts it:

*“We don’t see AI as a replacement of people—we view AI as force multipliers. We see AI as an ability and a technology to help us do our work faster, do our work better, do our work more consistently.”*

*He continues, “At the end of the day, development decisions are still made by people. That distinction between task automation and decision-making is really important... technology being an enabler of us being able to do our work better.”*

Viewed through this lens, the strategic value of AI and advanced analytics becomes clearer. When executed effectively, these technologies unlock capacity, surface insight earlier and accelerate decisions that might otherwise require weeks or months. They create the conditions for clinical development to move with greater predictability and confidence—delivering benefit not sporadically, but reliably and at scale.



## Interoperability must be about meaning, not just movement

One of the most nuanced and important themes to emerge from the Summit was the distinction between interoperability and harmonization.

For years, the industry has attempted to solve complexity by forcing data into uniform structures. Although well-intentioned, this approach often removes clinical and operational context—the very meaning required for reliable insight generation.

Interoperability is not about forcing all data into a single format or making every system look the same. It is about enabling systems to exchange information while preserving provenance, intent and context so that data remains meaningful as it moves across organizational and technological boundaries. Without this foundation, even the most powerful AI models are constrained, because intelligence depends on understanding, not on the sheer volume of data available.

Other complex, highly regulated industries have already learned this lesson. In financial services, for example, global payment and settlement systems succeed not because every institution uses identical data structures, but because shared standards preserve the meaning, source and purpose of each transaction as it moves across banks, geographies and regulators. In aviation, safety and performance depend on data flowing between aircraft, manufacturers and air-traffic systems with context intact.

Clinical development faces a similar challenge, but at greater human consequence. Patient data, operational signals and trial outcomes cannot be treated as interchangeable units to be standardized away. Their value lies in the circumstances under which they were generated and the decisions they are intended to inform. When interoperability preserves this context, AI can support earlier insight, more confident decisions and faster execution. When it does not, intelligence collapses into aggregation, creating noise rather than clarity.

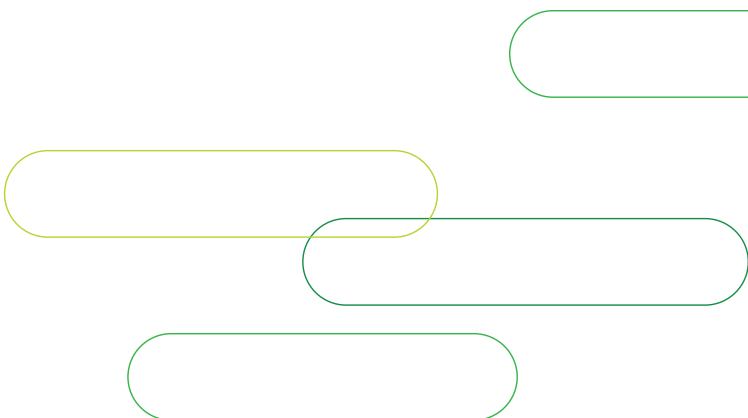
In this sense, interoperability is not a technical preference; it is a strategic prerequisite. Without it, AI remains limited to narrow use cases and retrospective analysis. With it, intelligence becomes portable, scalable and fit for purpose across the clinical development lifecycle. For intelligence to deliver value at scale, shared data meanings, transparent governance and collaboration are required. These are essential foundations for reliable, scalable AI across the industry.

## Incremental change is no longer enough. This breakpoint is pivotal.

The industry has reached a breakpoint, not a gradual transition. Incremental improvement (e.g., making existing processes slightly faster or cheaper) will not meet the demands of the next decade. The complexity of modern trials, the explosion of data and the expectations placed on sites and patients now require more profound change.

True transformation means breaking processes that once worked well but no longer scale. It means redesigning workflows around intelligence, not documents. It means moving forward with confidence rather than waiting for absolute certainty.

The FIT Summit reinforced Fortrea's belief that the future of clinical development will not be defined by who adopts technology first—but by who executes it best.





Execution demands bravery: challenging legacy models, investing in foundations rather than shortcuts and moving decisively while upholding trust and quality. It also requires collaboration—across sponsors, CROs, sites, regulators and technology collaborators—because no single organization can solve these challenges alone.

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