WHITE PAPER

From potential to practice: What will it take to make AI work in clinical trials?

A KEY QUESTION

What will it take for the clinical trials industry to move AI from isolated experimentation to scalable, system-wide adoption?

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For an industry built on scientific progress, clinical development finds itself in a moment of unusual hesitation. The artificial intelligence (AI), advanced data modeling and real-time analytics tools to transform trials are no longer theoretical—they are proven, available and increasingly integrated into pockets of the ecosystem. And yet, widespread adoption remains just out of reach.

It is as if the industry is waiting. Waiting for a bold innovator to move first. Waiting for a critical mass of partners to align. Waiting, perhaps, for an external shock—something on the scale of COVID-19—to force change through at speed. The floodgates are under pressure, but they remain only partially open.

This is not due to a lack of belief in AI. Quite the opposite. Across sponsors, CROs and technology collaborators, there is broad consensus that AI has the potential to accelerate trials, improve decision-making and bring therapies to patients faster. What is missing is not interest, but broad adoption. It is confidence in how to move from experimentation to execution and clarity on what it will take to embed these capabilities safely and effectively into the fabric of clinical trials.

The question, then, is no longer whether AI will reshape clinical development. It is what will finally unlock the shift from isolated innovation to industry-wide adoption—and whether that moment will be engineered deliberately or triggered by necessity.

The answer, it seems, lies not in any single breakthrough, but in a convergence of factors: Stronger data foundations, clearer governance, more disciplined investment and a redefinition of how trials are designed, delivered and experienced.

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Building pressure, but the break hasn't yet come

For an industry that prides itself on relentless scientific advancement, clinical development has arrived at a curious moment, one defined not by a lack of innovation, but by a lack of movement. The tools capable of reshaping trials are no longer emerging concepts, but operational realities. AI, advanced analytics and data-driven modeling are now embedded, at least in part, across the ecosystem. And yet, for all this activity, the industry feels suspended—poised but not yet in motion.

It is as if the sector is collectively waiting. Waiting for a single organization to move decisively and prove what is possible at scale. Waiting for a broader alignment, a coalition of stakeholders willing to take on the risk together. Or perhaps waiting, knowingly or not, for an external force to intervene, the kind of seismic shock that demands a response too urgent to resist.

This tension between readiness and action is now defining the trajectory of AI in clinical trials. It is no longer a question of capability. It is a question of what will finally cause the industry to act.

An illusion of progress: Innovation without adoption

The first source of confusion lies at the surface level: Activity that is mistaken for progress. The proliferation of pilots, innovation programs and AI-enabled use cases creates the impression that transformation is already underway.

Yet, many of the fundamental challenges of clinical trials remain stubbornly intact. Recruitment is still slow and unpredictable. Trial timelines continue to extend, costs remain high and complexity continues to increase. The gap between what is being demonstrated and what is being delivered has become increasingly apparent.

What the industry has achieved, therefore, is not transformation, but demonstration—it has demonstrated what is possible without yet embedding that possibility into practice. The result is a form of progress that feels real, but does not yet translate into systemic change. What the industry is experiencing, therefore, is not a failure to innovate, but a tendency to equate experimentation with transformation.

Reframing the problem: It was never about the technology

In the early enthusiasm surrounding AI, there was a tendency to treat the technology itself as the solution. The assumption, sometimes implicit, was that the application of advanced analytics and machine learning would, almost by default, resolve the inefficiencies embedded within clinical trials. Over time, that view has shifted, replaced by a more sober and far more useful understanding.

AI is not, in itself, transformative. It is, at best, an amplifier capable of enhancing whatever system it is applied to, but equally capable of magnifying its flaws.

The quality, relevance and structure of data matter just as much as the sophistication of the algorithms applied to it. Without the right inputs, even the most advanced technologies will struggle to deliver meaningful outcomes.

This reframing has profound implications. It moves the conversation away from technological potential and towards operational design and data interpretation. It asks not what AI can do, but how the industry needs to change in order to make AI effective. In doing so, it shifts responsibility away from the tools and back onto the system that produces and uses them. Moving beyond sporadic additions requires dedicated taskforce teams focused on embedding the technology across the organization, following a thorough gap analysis. Not every organization has the capacity to commit those resources (in capacity and technical knowledge). This remains relatively uncommon and is typically pursued only as part of broader company-wide strategic transformation initiatives.

From experimentation to execution: The floodgates won't break through experimentation

The consequence of these combined factors present another constraint. Not the lack of ideas, but the lack of deliberate selection and scaling. One of the defining characteristics of the current landscape is the sheer volume of experimentation. New ideas are constantly being tested, pilots are launched with increasing frequency and organizations are actively exploring multiple avenues of innovation at once. On the surface, this creates an impression of dynamism and forward momentum.

However, experimentation alone does not drive change. In many cases, it can in fact delay it. Without clear prioritization, defined objectives and a pathway to scale, initiatives remain contained within their original scope—proven, perhaps, but not propagated. The industry becomes highly proficient at learning without necessarily progressing.

Breaking through this cycle requires a shift in mindset. The focus must move from asking whether something works to asking whether it is worth scaling. That, in turn, demands discipline—clarity about the problems being solved, agreement on what success looks like and a willingness to deprioritize initiatives that do not meet those criteria. The floodgates will not open because more ideas are tested, they will only open when the industry starts executing on those that matter.

What is often missing is not experimentation, but a shared understanding of what qualifies as a scalable use case. Not every successful pilot should progress to broader adoption. To move from learning to execution, organizations increasingly need to apply a more disciplined lens. Does the use case address a structural bottleneck in trial delivery; can it integrate within existing workflows without introducing new operational burden; and does it generate outcomes that are measurable, reproducible and relevant across programs?

Without this level of selectivity, innovation risks remain fragmented. With it, organizations can begin to concentrate effort and investment on a smaller number of initiatives with the potential to create meaningful, systemic impact.

Adoption is the real barrier. And it is self-imposed

Beyond this surface-level activity, our next constraint lies within organizations themselves. Adoption is shaped less by technical feasibility than by internal risk perception and entrenched ways of working.

The industry is, by necessity, cautious. Apart from impact on commercial outcomes, patient safety, data integrity and regulatory compliance are non-negotiable, and for good reason. Yet this caution can extend beyond what is required, creating a reluctance to adopt new approaches even when their value is understood. Proven processes are repeated, not because they are optimal, but because they are familiar and already proven acceptable.

In this sense, the barrier to adoption is largely self-imposed. It is not that the industry cannot move, but that it is not yet willing to move at the pace that its capabilities would allow. If it's not broken, don't fix it.

Why change feels slow: The reality of risk and incrementalism

To fully understand the current state of adoption, it is important to recognize the structural realities of clinical trials. Unlike other industries where transformation can be rapid and iterative, clinical development operates within a framework where the cost of error is exceptionally high and where the impact materializes lately.

Introducing change, therefore, is not simply a technical decision, it's a risk decision.

As a result, innovation tends to follow an incremental path. New approaches are introduced cautiously, often in early-stage studies, where the consequences of failure are more manageable. As confidence builds over time, these approaches are extended into more critical phases of development. While this process ensures rigor, it also creates a natural drag on the pace of change.

This does not mean that acceleration is impossible. Rather, it highlights the need for mechanisms that reduce perceived risk—whether through better evidence, clearer governance or shared experience. Without these, even the most compelling innovations will struggle to move beyond the margins.

The system problem: Too many players, not enough alignment

Even where organizations are willing to move, a third constraint emerges at the system-level. Clinical trials are delivered through a network of interdependent stakeholders whose incentives are not always aligned. Sponsors, CROs, sites, technology providers and regulators all play a role in shaping how trials are designed and delivered. This diversity is a strength, but it also introduces complexity.

While there is often broad agreement on the challenges facing the industry, there is less consensus on how to address them. Different stakeholders approach the same problem from different angles, leading to fragmentation rather than convergence. Without alignment, even well-intentioned efforts can fail to scale, as each part of the system evolves independently.

Transformation cannot be achieved in isolation. It requires coordination across the ecosystem—shared objectives, aligned incentives and a willingness to collaborate in areas that have traditionally been competitive.

The inflection point: Where pressure could finally break through

If the industry is indeed building towards a point of breakthrough, the question becomes what form that breakthrough will take. While the exact trigger is difficult to predict, there are several pathways through which change could accelerate.

Trigger pathway one: A lead mover

The first possibility is the emergence of a lead mover. An organization willing to move beyond experimentation and implement AI-driven approaches at scale. If that organization can demonstrate measurable improvements in speed, efficiency or outcomes, it will create a powerful precedent. In a competitive environment, such proof points are difficult to ignore and others are likely to follow.

Trigger pathway two: Coordinated industry action

A second pathway lies in collective action. By bringing together multiple stakeholders across sponsors, providers and regulators, the industry can reduce the perceived risks associated with change. Shared frameworks, common standards and pre-competitive collaboration can create a foundation upon which innovation can be scaled with greater confidence.

Trigger pathway three: External shock

The third pathway is less controlled. External shocks, whether they are global health crises, economic pressures or systemic disruptions, have the capacity to accelerate change in ways that incremental efforts cannot. When urgency is imposed from outside, barriers that once seemed insurmountable can fall away quickly.

What needs to be in place before the breakthrough

Regardless of which pathway ultimately prevails, the industry must be prepared. Unlocking widespread adoption is not simply a matter of triggering change, it requires a system capable of absorbing it.

This preparation begins with data. Not more data, but better data, relevant, structured and aligned with the questions being asked. It extends to governance, ensuring that AI is applied within clear, robust frameworks that support both innovation and compliance. And it requires a sharper focus on value, prioritizing use cases that deliver tangible benefits over those that are merely interesting.

Without these foundations in place, even the most dramatic breakthrough will struggle to sustain itself.

From readiness to adoption: A practical lens

As organizations move from preparing for change to implementing it, a small number of conditions appear consistently in environments where adoption begins to successfully scale:

- **Clarity of purpose:** A well-defined problem linked to a measurable outcome, rather than a broad ambition to “apply AI”
- **Data relevance, not just data volume:** Datasets that are relevant, structured and aligned with the decision being supported
- **Operational integration:** Solutions that fit within existing workflows and roles, rather than creating parallel processes
- **Evidence that reduces perceived risk:** Demonstrable, repeatable outcomes that build confidence beyond isolated pilots
- **Alignment across stakeholders:** Shared incentives between sponsors, CROs and collaborators on where value is created and how it is measured

These conditions do not eliminate complexity, but they provide a practical lens through which organizations can prioritize efforts and move from isolated success to broader adoption.

The human shift: Patients and decision-making are changing faster than trials

While much of the focus has been on technology, one of the most significant forces reshaping clinical trials lies elsewhere—in the evolution of patient behavior and decision-making.

Patients today are more informed, more connected and more active participants in their healthcare journeys.

Their expectations of transparency, accessibility and relevance have increased, and their engagement with trials is influenced not only by clinical criteria, but by cognitive, emotional and contextual factors that traditional trial designs have often overlooked.

This shift introduces a critical consideration for the application of AI. Algorithms trained solely on operational or clinical data can optimize processes, but may fall short in predicting how patients perceive, engage with and ultimately participate in trials. Bridging this gap required integrating behavioral understanding into the way trials are designed, modeled and executed.

In this context, the effective use of AI is not only about improving efficiency but about aligning trial design more closely with real-world patient behavior. Organizations that are able to combine robust data foundations with a deeper understanding of human decision-making are likely to be better positioned to translate technological capability into tangible improvements.

Conclusion: The inevitable shift from waiting to acting

The industry stands at a point where its capabilities and its actions are no longer aligned. The potential of AI is understood, the barriers are increasingly well defined and the need for change is growing more urgent by the day.

What remains is a decision.

Will the sector continue to wait for proof, for alignment or for necessity to force its hand? Or will it begin to act, deliberately and collectively, to translate potential into practice? The demands placed on clinical trials will only increase, and with them, the cost of inaction. At some point, the balance will shift.

For some organizations, this shift has already begun. The combination of clearer prioritization, stronger data foundations and a more integrated view of trial design is starting to translate into measurable progress. The question is less whether change is possible, and more how quickly others will follow.

The floodgates will not open by accident. They will open when the industry decides that waiting is no longer the safer option, and that the future of clinical trials depends not on what could be done, but on what is done next.

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