AI Teammates Impact on Clinical Research

Clinical research is in a pivotal moment. Over the past two decades, we've witnessed extraordinary advances in biology, genomics, and drug discovery. Yet the infrastructure supporting clinical trial execution has not kept pace. Despite breakthroughs at the molecular level, the operational backbone of drug development remains manually intensive, fractured by point solutions, and heavily reliant on an overstretched workforce.

Artificial intelligence offers a way forward through "AI teammates": specialised, operationally grounded AI systems designed to work alongside coordinators, clinical operations staff, and sponsor teams to reduce site burden, automate compliance, improve data quality, and ultimately accelerate access to new therapies.

From our experience working across sponsors, CROs, and sites, we believe AI teammates are more than simply the next innovation wave. They are quickly becoming a prerequisite for the next chapter of biopharma growth.

The Bottleneck: Not Discovery, But Delivery

The burden of operational complexity has become one of the most limiting factors in modern clinical research. Investigators report that their coordinators are routinely re-entering the same data across multiple portals, manually tracking protocol amendments, and juggling redundant documentation requirements.[1,2] These are everyday realities that prevent sites from expanding capacity. This is the real crisis. While the industry debates decentralised trial designs or the promise of synthetic control arms, the coordinators at the heart of trial execution are spending late nights reconciling PDFs, formatting logs, and chasing signatures. It's no wonder that turnover at research sites remains stubbornly high.

AI teammates offer a lifeline. Not by replacing these staff, but by relieving them of repetitive, low-value work and giving them more time for protocol adherence, patient care, and communication. By offloading even a portion of this work to AI-enabled systems, sites report being able to take on additional studies without risking burnout among staff.[1,3]

The AIQ Imperative

A pharma company's Artificial Intelligence Quotient (AIQ) is a way to measure its ability to adopt, integrate, and scale AI across the clinical research lifecycle.[4] Just as digital maturity once separated early software leaders from laggards, AIQ now distinguishes those who can run faster, more efficient trials using AI from those who are not adopting it.

For companies that have a portfolio of rare disease studies that must be managed in parallel, the ability to move quickly and confidently is critical. That's where AIQ can be a real competitive advantage. One such example is Opus Genetics (NASDAQ: IRD), a gene therapy company based in Raleigh, NC. AI teammates support key operational workflows, allowing it to not only gain execution speed but also better data integrity and decision-making confidence.[5] In the current capital-constrained environment, this is an increasingly important strategic differentiator.

For Opus, the strategic value of AI teammates goes beyond time savings. They allow sponsors to de-risk development by enabling earlier detection of site issues, protocol deviations, and operational gaps. That has significant implications. Investors are increasingly looking for operational leverage in addition to scientific novelty. Sponsors who can demonstrate high AIQ and superior operational efficiency, made possible by embedding AI into trial execution, will be in a stronger position to raise follow-on capital in a difficult funding environment.[6]

From Fragmentation to Integration

One of the major reasons clinical research has failed to scale is the proliferation of disconnected platforms. The typical research site today juggles a dozen different systems (including CTMS, eSource, EDC, IRB portals, email threads, etc.) and many of these do not talk to each other.

In contrast, AI teammates are designed to seamlessly function across systems. They monitor inboxes for IRB updates, extract protocol changes from PDFs, update tracking logs, and even initiate downstream workflows. They are the operational scaffolding enabling sponsors and sites to work in sync without overloading already-stretched teams. For example, at Georgia Retina, Dr. David Chin Yee notes that task automation through AI has reduced coordinator workload, improved query turnaround times, and accelerated first-patient-in milestones.[2]

Importantly, adoption of AI teammates should be low-friction by design: they should plug into existing systems and SOPs, so roles, approvals, and RACI stay unchanged. Change management becomes a matter of simple SOP addenda and thresholds so that the transition is quick, auditable, and predictable.

As Dr. Houman Hemmati, clinical development executive and founder of Optigo Biosciences stated: "Our industry has over-indexed on building systems and under-invested in the glue. AI is finally giving us that connective tissue".[7] In other words, AI teammates don't replace platforms. They make them work together.

AI's Measurable Impact on Sites

Among the most immediate and measurable gains of AI are happening at the site level. Clinical research sites have long been burdened with redundant documentation, staff shortages, and overwhelming regulatory requirements. "Chasing paper" is one of the most time-consuming aspects of clinical trials for site staff. By offloading repetitive administrative tasks (such as reconciling deviations, entering duplicative data, or manually checking protocols), AI teammates are vastly improving both quality and efficiency.

For example, Dr. James Fox of ICON Eyecare reports that, within three months of implementation of AI, his site experienced a 47% decrease in data entry time, 31% improved query response time, and a reduction of manual queries per site of 42%. In addition, he noted that study startup processes accelerated significantly, with templates, reg binders, and delegation logs prepared in hours instead of days.[8]

Dr. Chin Yee describes this as "giving time back to our coordinators," allowing his team to handle more trials without increasing burnout.[9] AI is making regulatory compliance and documentation more automated, auditable, and accurate, which, in turn, helps sites improve quality while expanding their capacity.

AI helps by surfacing critical requirements in real time, flagging missing labs, reminding teams of patient visit windows, or catching subtle protocol deviations before they escalate. This operational intelligence layer doesn't just improve compliance; it boosts confidence. Staff feel more supported. Investigators trust their data. And sponsors get cleaner results, faster.

Sites are no longer passive recipients of technology but active beneficiaries. As AI becomes embedded in daily workflows, the best-performing sites won't be the ones with the most headcount, but the ones who've figured out how to work smarter with it as an internal teammate.

Regulators Are Already There

A common concern from industry executives about technology in general, and AI in particular, is: what will the FDA think? The answer is that they're already using AI themselves.

The FDA's recent deployment of ELSA (Enhanced Lifecycle Submission and Analysis) is a signal that regulatory agencies aren't waiting for the industry to modernise.[10] In a rare circumstance, FDA is leading the modernisation effort starting with applying AI to streamline review processes. This creates a subtle but important shift: if regulators are using AI to evaluate submissions, then what steps do sponsors need to take towards adoption of AI? The answer varies for each organization, but it is something that needs to be considered going forward.

We believe that sponsors with higher AIQ, those able to deliver well-structured, traceable, and real-time data, will be better positioned in future regulatory interactions. They'll also be better prepared for inspections, audits, and data lock processes.

Implications for CROs

As FDA moves forward, and as AI teammates take on increasingly sophisticated co-ordination and compliance tasks, sponsors are reevaluating their needs from CROs. What they want is flexibility, speed, and visibility. Sponsors will begin asking harder questions going forward, and evaluating who can actually help them move faster.

This is an opportunity for innovative CROs to stand out, and leapfrog ahead. Those who embrace AI teammates as a force multiplier, streamlining workflows, enabling real-time risk mitigation, and improving site support, can become even more strategic partners. But those who resist may find themselves bypassed by sponsors building agile, tech-enabled internal ops teams.

From Adoption to Differentiation

AI teammates are not a silver bullet. They require thoughtful implementation, training, and change management. But the gap between proof-of-concept and production deployment is closing. What used to be futuristic is now live across dozens of trial sites.

More importantly, the benefits are cumulative. A site that uses AI to reduce its regulatory burden is more likely to take on additional studies. A sponsor that uses AI to detect risk signals early is more likely to hit milestones. An executive team that moves up the AIQ curve is more likely to secure follow-on funding and scale its portfolio.

2026 is the year of the tipping point for AI in clinical research. As Dr. Hemmati observed, "AI is no longer an experiment. It's an accelerant".[7]

The Path Forward

For clinical research to keep pace with scientific innovation, the industry must rethink not just what it studies, but how it runs studies. That means investing in systems that scale so that headcount doesn't burn out. It means treating AI not as yet another technology but as a strategic enabler. And it means recognizing that sponsors with higher AIQ will have a measurable advantage in speed, efficiency, and ultimately, patient impact. We believe that AI teammates are the infrastructure we've been waiting for.

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