AI in Clinical Trial Recruitment:
Proceed with Cautious Optimism

Artificial Intelligence (AI) is rapidly reshaping the landscape of clinical research, offering transformative solutions to longstanding challenges in trial design, execution and data management. As of 2025, AI is no longer a futuristic concept; it is a practical tool driving efficiency, precision and innovation across the clinical trial ecosystem. But what does AI mean in the context of practical applications for day-to-day clinical development activities? And does its potential have any limits?

Patient recruitment remains one of the most persistent challenges in clinical research, with up to 80% of trials failing to meet enrolment timelines and nearly one-third of Phase III trials being terminated due to insufficient accrual. In this context, AI offers a compelling opportunity to reimagine how patients are identified, engaged and retained. Yet, as with any powerful tool, its use must be tempered with ethical foresight and operational realism. This editorial explores the promise, limitations and future direction of AI in clinical trial recruitment.

The Evolution of Recruitment Challenges

Historically, patient recruitment has been a consistent operational challenge in clinical trials. Traditional methods including physician referrals, site databases and advertising campaigns, often resulted in slow enrolment, high dropout rates and underrepresentation of diverse populations. Despite incremental improvements, recruitment delays continue to cost sponsors millions annually and jeopardise study timelines. These persistent challenges underscore the need for innovative, data-driven approaches to recruitment, where AI, in particular, is emerging as a transformative force in this space.

Practical Applications of AI in Clinical Development

The use of AI has already made significant strides in optimising activities that previously required extensive human time and effort. Tasks that once took weeks can now be completed in a fraction of the time. AI-powered machine learning (ML) models are being used to predict trial outcomes and identify risks such as protocol failure or patient dropout. These models analyse both structured and unstructured data from past trials, such as eligibility criteria and geographic distribution, to forecast potential issues before they arise.

Generative AI, with its own set of use cases, is being used to create initial drafts of protocols and lengthy documents, shifting the human contributor's role from creator to editor. These advancements have emerged rapidly, especially when compared to the decades-long reliance on traditional processes that saw only minor changes, such as the transition from paper to digital formats.

AI's Role in Recruitment: Promise and Limitations

Despite decades of effort, recruitment continues to be a major operational hurdle in clinical trials. AI technologies are now being applied to address this issue with greater speed and precision than ever before. Tools such as chatbots and predictive algorithms are improving patient matching by analysing electronic health records (EHRs), demographic data and even genomic information. For example, platforms like TrialGPT have demonstrated near-human accuracy in identifying eligible participants, reducing screening time by over 40%. Beyond identification, AI also supports patient engagement through personalised reminders, educational content and real-time support, factors that contribute to improved retention and overall satisfaction.[3,4]

Manual review of patient charts is time-consuming and prone to error. AI's ability to synthesise disparate data sources, including clinical, demographic and behavioral, into a unified view is a clear advantage. These capabilities are particularly valuable in reducing site burden, supporting feasibility assessments and increasing certainty of eligibility for external site referrals through middleware[5] solutions that bridge patient record retrieval.

However, one area that remains unexplored is AI's ability to predict human behavior beyond eligibility. While AI can determine who qualifies for a trial, it cannot yet reliably predict who will choose to enrol. The decision to participate is influenced by a complex mix of factors: site engagement, study design, time commitments, cultural attitudes and even external events like pandemics. This raises an interesting question: Can AI not only identify eligible patients but also predict which ones are most likely to consent? Answering this question is, at best, a tentative 'maybe.' Exploring its feasibility introduces deeper philosophical and ethical questions.

Ethical and Philosophical Considerations

- Is it possible for AI to use currently available data to make predictions, or are additional inputs, such as social determinants of health or consumer behavior required?
- What characteristics influence a patient's willingness to participate and can these be objectively characterised?
- Should an individual's online footprint be considered and if so, how do we safeguard privacy?
- What are the boundaries of patient trial matching and prediction done without consent versus requiring explicit authorisation?

Some of this data could theoretically be scraped from the internet and integrated with clinical datasets, but this raises concerns about appropriateness and consent. Should AI be allowed to mine consumer behavior or social media activity to predict trial participation? And if so, should these applications be limited to HIPAA-covered entities, or can commercial recruitment organisations with AI offerings also participate?

The deeper AI applications go into the lives of potential participants, the greater the responsibility to protect those individuals, even if the use cases seem benign, such as sending a trial invitation. The integration of consumer data with health information is a murky area that demands careful scrutiny.

AI Bias and Fairness in Recruitment

One of the most pressing concerns in AI-driven recruitment is the risk of algorithmic bias. If training data lacks diversity, AI models may inadvertently exclude underrepresented populations, reinforcing existing disparities in clinical research. For example, an AI tool trained primarily on data from urban academic centers may underperform in rural or minority communities. Ensuring fairness requires deliberate

efforts to audit models, diversify training data and include equity metrics in performance evaluations.

Human-in-the-Loop Models

Despite AI's growing capabilities, human oversight remains essential. The 'human-in-the-loop' models, where AI suggestions are reviewed and validated by clinical staff, offer a balanced approach. This ensures that nuanced clinical judgement, ethical considerations and patient preferences are not lost in automation. These hybrid models are especially valuable in sensitive areas like recruitment, where trust and empathy play a critical role.

Regulatory Perspectives

Regulatory bodies are beginning to address the implications of AI in clinical research. The FDA's recent draft framework[6] for AI/ML-based software emphasises transparency, validation and patient safety, all principles that must extend to recruitment algorithms. Similarly, the European Medicines Agency (EMA)[7] has signaled interest in developing guidelines for AI use in clinical trials, particularly around data integrity and ethical considerations.

These frameworks are still evolving, but they underscore the need for industry-wide standards. Without clear guardrails, the risk of misuse or overreach grows, potentially undermining public trust in clinical research.

Global Perspectives on AI in Recruitment

Globally, the adoption of AI in clinical trials varies widely. In the U.S., innovation is often driven by private sector investment, while the EU emphasises ethical frameworks and data protection under GDPR. In Asia, countries like China and South Korea are rapidly scaling AI infrastructure, with government-backed initiatives supporting AI in healthcare. These regional differences influence how AI is applied in recruitment, from data access to regulatory scrutiny.

The Patient Perspective

From the patient's point of view, AI-driven recruitment may feel impersonal or even invasive. Transparency about how data is used and ensuring informed consent at every stage, is critical to maintaining trust. Patients must understand not only that they are eligible for a trial, but also how and why they were identified. This is especially important in communities with historical mistrust of medical research, where even well-intentioned outreach can be met with skepticism.

Unfortunately, the history of clinical research includes instances of unethical behavior that have left lasting scars, particularly among marginalised populations. As AI becomes more embedded in recruitment strategies, it must be wielded with sensitivity and respect for these historical contexts.

Real-World Examples

Several AI tools are already demonstrating the potential to improve recruitment outcomes. Deep 6 AI8, for example, has partnered with academic medical centers to accelerate patient matching by mining EHRs in real time. In one pilot study, recruitment timelines were shortened by 30% and site staff reported improved confidence in feasibility assessments.

Another example is IBM Watson Health,[9] which has explored AI-driven trial matching using natural language processing to interpret complex eligibility criteria. While technology shows promise, it also highlights the importance of human oversight, AI can suggest matches, but clinical judgment remains essential.

Interoperability and Data Integration Challenges

For AI to be effective in recruitment, it must access and interpret data from multiple sources, including EHRs, claims data, registries and more. However, interoperability remains a major challenge. Variability in data formats, coding standards and system architectures can limit AI's ability to generate accurate insights. Industry-wide efforts to standardise data exchange, such as Fast Healthcare Interoperability Resources (FHIR), are critical to unlocking AI's full potential.

Looking Ahead: A Call to Action

As AI continues to evolve, the clinical research industry must prioritise responsible innovation. Establishing cross-functional working groups, including technologists, ethicists, regulators and patient advocates, can help define best practices and ensure AI serves both science and society.

CROs, sponsors, technology companies, healthcare institutions, sites and patient representatives all have a role to play in shaping the future of AI in recruitment. Together, they must ensure that innovation does not come at the expense of ethics, transparency, or patient trust.

AI has the potential to transform the patient recruitment process, but its success will depend on how thoughtfully it is implemented. The industry must remain vigilant, collaborative, and committed to keeping patient experience at the center of every technological advancement.

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