

Views and Opinions

Patient perspective



From smarter algorithms to more patient-centric trials: Balancing AI innovation and the patient perspective in clinical research

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Clinical trials face persistent structural challenges. Recruitment delays affect the majority of studies, data quality issues remain widespread, and administrative complexity continues to grow. Evidence suggests that artificial intelligence (AI) applications can meaningfully address many of these bottlenecks.¹ Machine learning and natural language processing have demonstrated the ability to improve patient recruitment rates by up to 65%, reduce trial timelines by 30–50%, and enhance adverse event detection through continuous monitoring and digital biomarkers.¹ AI is also increasingly being used to optimise protocol design, reduce administrative burden, and support adaptive trial designs.² These gains, however, are accompanied by new uncertainties. Patients increasingly ask not only what technologies are used in trials but how, by whom, and in whose interests. Addressing these questions is essential if AI is to support genuinely patient-centred clinical research.

Participation that fits real life: AI's potential to reduce patient burden and expand inclusivity

For trial participants, AI-enabled recruitment tools can improve matching between individuals and relevant trials, thus reducing the frustration of ineligible enrolment and repeated screening failures.³ When implemented well, AI tools can make trial participation feel more purposeful and respectful of patients' time and circumstances.

Patients may also benefit from AI-powered remote monitoring and digital biomarkers (patient-generated health data collected through wearables, smartphones, and connected sensors that can provide continuous insights into symptoms, behaviour, and treatment response). Continuous data collection via wearables or mobile devices can reduce the need for frequent site visits, making participation more feasible for people with mobility constraints or caregiving responsibilities and for those living far from research centres.^{1,4} This is particularly relevant for decentralised or hybrid trial models, which are increasingly positioned as more patient-centric alternatives. There is also evidence that AI-supported monitoring (i.e. when AI continuously interprets patient-generated data – such as fatigue, heart rate, mobility, sleep, or medication adherence – from wearables, apps, and symptom diaries) can improve safety surveillance by detecting early signs of adverse events and enabling more timely, personalised responses from trial teams.^{1,4} Fewer site visits and more flexible data collection can lower the practical burden of participation; for patients, this can mean that contributing to research no longer causes substantial disruption to their daily lives.

There is also cautious optimism that AI could support more inclusive trials. This does not mean, however, making study populations arbitrarily more heterogeneous at the expense of scientific validity or patient safety. It is necessary that clinical trials define eligibility criteria to ensure internal validity, minimise confounding, and protect participants from unnecessary risk. Yet traditional recruitment approaches can unintentionally under-represent certain patient groups (such as older adults, women, ethnic minorities, or people in rural settings), even when they fall within the intended target population.

AI-driven approaches, including electronic health record screening and federated learning, may help identify eligible participants more systematically and reduce access barriers, thus potentially improving representativeness within predefined study criteria. This could strengthen the external validity of findings while preserving scientific rigour, provided that underlying data biases are recognised and actively addressed.^{1,5}

When efficiency outpaces understanding

Despite its potential, using AI in clinical trials raises concerns that resonate strongly with patients and the wider public. A recurring theme is that many AI systems remain opaque, even to healthcare professionals.^{6,7} For participants, this opacity can undermine informed consent. If AI influences eligibility decisions, safety monitoring, or outcome assessment, patients reasonably expect to understand its role in a meaningful way.

Without clear explanations, consent risks becoming a formality rather than a process grounded in understanding. This is particularly problematic in trials involving adaptive designs, where AI systems may evolve over time.

Data, control, and the question of trust

AI-driven research relies heavily on access to large volumes of personal health data. While regulatory safeguards provide an essential baseline, compliance alone does not resolve public concerns.⁸ Patients are increasingly asking who controls their data, how long their data will be used, and whether data may be repurposed beyond the original study.⁹

Trust is further strained when AI tools are introduced without clear accountability structures. Persistent uncertainty remains around liability and governance, particularly when AI systems inform decisions affecting participant safety (such as detecting adverse events, triggering protocol adjustments, or recommending clinical interventions). The development, validation, deployment, use, and oversight of AI systems

in AI-enabled clinical trials may involve multiple stakeholders, including sponsors, investigators, clinicians, AI developers and other service providers, independent data monitoring committees, ethics committees, and regulators. The involvement of multiple actors may complicate the allocation and documentation of operational roles, including system validation, performance monitoring, human review, incident escalation, and vendor oversight. These responsibilities and escalation pathways should therefore be explicitly defined when AI-generated outputs contribute to clinical or operational decisions.¹⁰ For patients, knowing who is responsible when something goes wrong is not a legal abstraction; it is central to their willingness to participate in a trial.

Bias is not a technical footnote

Algorithmic bias remains a critical challenge. If AI systems are trained on datasets that under-represent certain populations, they risk perpetuating or amplifying existing inequities. This is not an abstract concern for patients: biased recruitment or outcome prediction can directly affect who is invited into trials and whose outcomes are prioritised.

Evidence shows that many AI applications proposed for use in clinical research have not been adequately trained and externally validated using datasets that represent diverse demographic and clinical populations.^{11,12} Sponsors and investigators should therefore assess whether the data used to develop and validate an AI system are sufficiently representative of the intended trial population and context of use. For participants, this raises a fundamental question: Does AI make research more equitable? Or does it risk amplifying existing disparities?

AI for IMPACTS framework: A holistic guide for meaningful AI use

Addressing these challenges requires more than technical fixes. It requires a structured, holistic evaluation of AI tools that extends beyond technical performance metrics. It requires structured ways to evaluate whether AI technologies deliver meaningful, trustworthy value in real-world research settings. Many

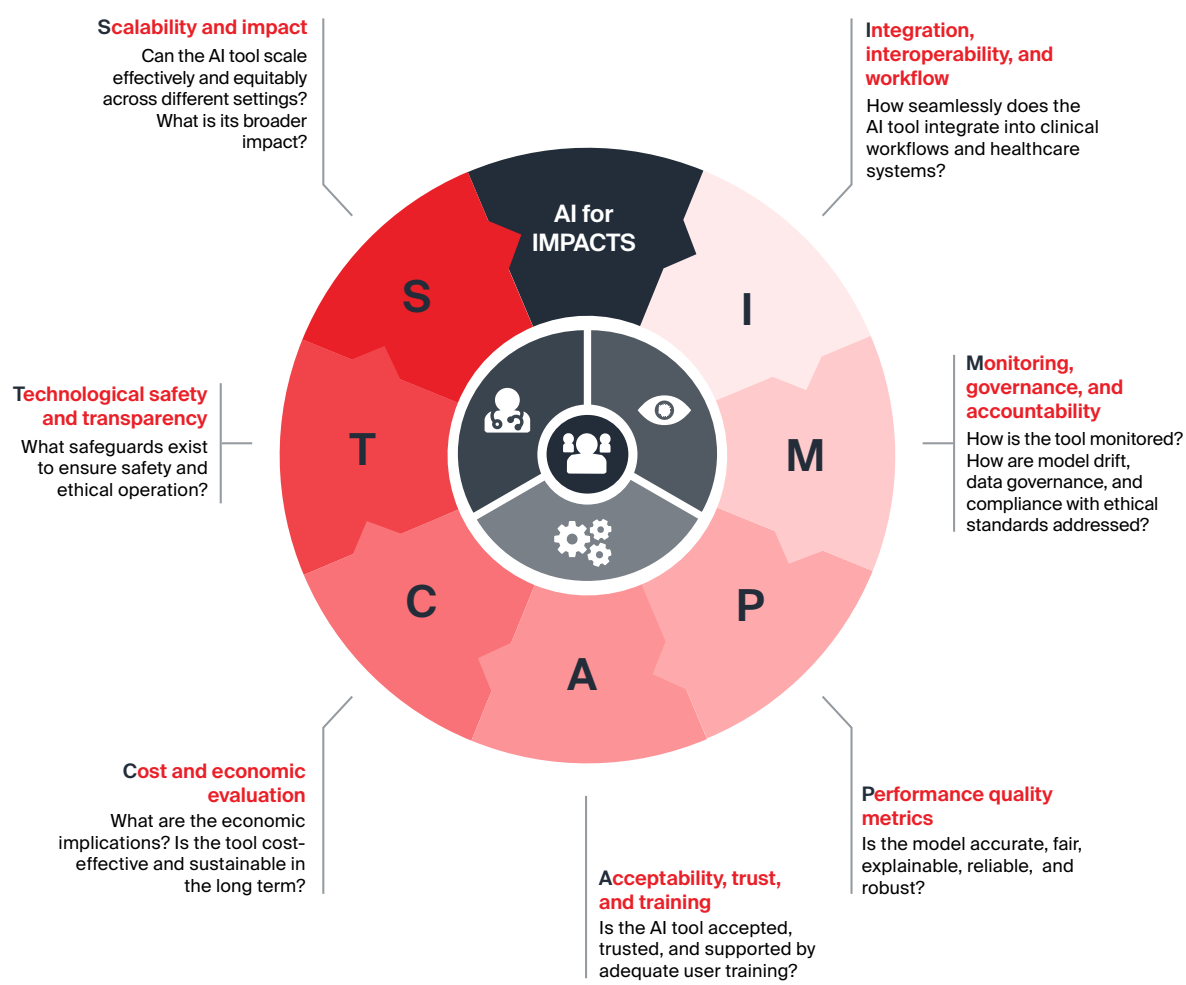
AI assessment guidelines, however, remain narrowly focused on accuracy or methodological rigour and neglect social and organisational dimensions.¹³ In response to this gap, the AI for IMPACTS framework was developed through a collaborative effort involving several Swiss universities as well as clinical and AI experts.¹³ The framework is organised around seven assessment clusters that form a holistic checklist for evaluating AI tools beyond technical metrics, as illustrated in **Figure 1**:

- **I**ntegration, interoperability, and workflow
- **M**onitoring, governance, and accountability
- **P**erformance and quality metrics
- **A**ceptability, trust, and training
- **C**ost and economic evaluation
- **T**echnological safety and transparency
- **S**calability and impact.

By using such a framework as a checklist during trial design and procurement, research teams can systematically ask not only “Does this AI work?” but also “Does this AI create value that patients recognise and trust?” To be maximally useful in clinical research, AI assessment should explicitly place patients at the centre of the evaluation:

- Acceptability, trust, and training should explicitly assess whether participants understand the role of AI in a trial and whether they feel confident raising concerns or questions.
- Monitoring, governance, and accountability should include clear, patient-facing explanations of responsibility, data use, and recourse in the event of errors or harm.
- Performance and quality metrics should incorporate patient-relevant outcomes, such as reduced burden, perceived fairness, and any impact on the participation experience.
- Scalability and impact should evaluate whether AI-enabled trial models remain inclusive as they expand, rather than privileging digitally confident or well-resourced participants.

Figure 1: AI for IMPACTS framework



Source: Adapted from [Jacob C et al. \(2025\)](#), Figure 3¹³

Conclusion: Aligning innovation with its value to patients

AI has the potential to make clinical research more efficient, adaptive, and inclusive. From a patient and public perspective, however, its legitimacy depends on trust, transparency, and perceived fairness. The evidence suggests that while AI can improve how trials are run, it can also exacerbate existing concerns if introduced without sufficient oversight and engagement.

Frameworks such as AI for IMPACTS offer a practical way forward by embedding patient-relevant considerations into AI evaluation from the outset. For regulators, sponsors, and research teams, the challenge is no longer whether AI can be used in clinical research but whether it is used in ways that patients and the public experience as meaningful, ethical, and trustworthy.

Key Takeaways

AI in clinical research is not only a technical innovation – it is a shift in how participants experience, understand, and trust trials.

Efficiency gains are not sufficient on their own. Demonstrated improvements in recruitment, monitoring, or timelines must be complemented by evidence that using AI reduces participant burden, supports safety, and delivers patient-relevant value.

Transparency must extend not only to reviewers but also to participants. Informed consent processes should clearly explain where AI is used in a trial, what role it plays in decision-making, and what remains under human control.

Governance and accountability should be visible to patients. Clear responsibility for AI-related decisions, errors, and data use should not only be documented in protocols but also defined and communicated in accessible terms to participants.

Bias and representativeness require proactive oversight. AI tools should not be treated as neutral or self-correcting technologies; they should be assessed for their impact on inclusion, fairness, and population diversity across the trial lifecycle.

Evaluation frameworks can help operationalise patient-centred AI. Holistic approaches such as the AI for IMPACTS framework support decision makers in moving beyond technical validation toward assessing real-world, patient-relevant impact.

Early, structured evaluation reduces downstream risk. Conducting a patient-focused AI assessment during trial design and procurement can prevent costly redesigns, regulatory delays, and a loss of participant trust later in the research process.

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