

Views and Opinions

Clinical trial management



Incorporating artificial intelligence into clinical trial management

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doi: [10.54920/SCTO.2026.RAWATCH.11.38](https://doi.org/10.54920/SCTO.2026.RAWATCH.11.38)

Artificial intelligence (**AI**) is transforming many industries, and healthcare and clinical research are no exceptions. In clinical research, AI holds significant potential to streamline trial management. It can be used, for example, to evaluate trial feasibility and facilitate document creation, support patient recruitment, strengthen quality and safety monitoring, and enable real-time assessment of trial progress and outcomes. Yet if AI is to truly advance the quality of clinical research, its integration must be approached with caution and reflection – with regard to not only its technical feasibility but also its broader ethical implications. This article explores different aspects of using AI systems in clinical trial management, including ethical blind spots, trade-offs, structural implications, uncertainty in regulation, and interdisciplinary collaboration.

Ethical implications of using AI in trial management

At first glance, using artificial intelligence (AI) to make clinical trial management more efficient may not appear to raise profound ethical concerns. Trial management is often perceived as the administrative backbone of research that, in theory, could be efficiently automated. In an era where clinical trials are becoming increasingly complex and costly, increased automation is undeniably attractive. This perception, however, is misleading. In clinical trials, even seemingly administrative decisions can have direct consequences for participants' health. For example, if an AI system is used to support patient recruitment, the way it determines eligibility may directly influence who gains access to a novel therapy and who does not – and thus who may face the associated risks and receive the potential benefits.

Implications extend even beyond the individual level. Clinical trial results affect regulatory approvals and clinical treatment recommendations. The data generated must therefore be accurate, trustworthy, and reproducible. Importantly, clinical trial outcomes are also determined by trial management decisions. When embedded in these processes, AI inevitably becomes part of the epistemic foundation of medical evidence.

Efficiency and its ethical blind spots

Much of the current literature on using AI in clinical trials focuses on efficiency and accuracy. Yet an exclusive emphasis on efficiency risks obscuring deeper ethical questions. A critical lesson from my research is that not all AI applications are equally suitable for clinical trial management.^{1,2,3,4} AI's entry into this field can sometimes challenge traditional notions of autonomy and accountability.

Autonomy refers to participants' ability to make informed and voluntary decisions about their involvement. This is particularly relevant in the context of AI-based screening of participants from electronic health records. Participants may not even be aware that AI tools are being used to assess their eligibility for a trial or that their health data are accessed and processed for this purpose. This raises fundamental questions about transparency and informed consent.

Accountability presents another challenge. There is a common assumption that ethical concerns can be resolved through human supervision. Oversight, however, is not a simple remedy. Over-reliance on AI can reduce vigilance and weaken critical evaluation. Additionally, supervisors without sufficient AI literacy may not fully understand model behaviour, data provenance, or system limitations. In such cases, human oversight becomes formal rather than substantive.

Trade-offs and structural implications

Efficiency gains are not without trade-offs. While AI may reduce researchers' workload, it can also contribute to the dehumanisation of research processes. The relationship between researchers and participants is built on trust, empathy, and dialogue. Some tools, such as AI-powered chatbots used for patient screening and algorithm-driven patient monitoring systems, may risk weakening this relational dimension by reducing direct interactions between clinicians and patients and thereby limiting opportunities to have meaningful communication and build trust. In addition, as reliance on AI grows, critical competencies – such as clinical reasoning, ethical sensitivity, and attentiveness to subtle clinical signs – may erode, making it more difficult to detect errors or challenge algorithmic outputs.⁵ This creates a paradox: systems intended to support researchers may ultimately reduce their capacity to exercise independent judgment.

The responsible use of AI in clinical trial management therefore requires a broader perspective. It cannot be evaluated solely in terms of performance metrics. Instead, we must consider how these technologies reshape relationships among researchers, participants, and institutions – and how they influence trust, responsibility, and researchers' professional identity. It is also important to acknowledge the substantial resources required for AI development, adaptation, and validation. Even though AI may simplify certain processes, without robust governance and strategic planning it risks adding complexity in other areas and increasing costs.

Striking a balance between uncertainty and the risk of reactive or excessive regulation

Regulators acknowledge that AI introduces new layers of complexity into healthcare and clinical research and have therefore started to revise existing frameworks in order to respond to technological developments. Yet progress has been cautious, and significant uncertainties remain. Key questions are still unresolved: How should AI-driven trial management tools be classified within existing regulatory categories? Must patients be informed when such tools are used – and if so, in what form? Should AI systems be explicitly declared in submissions to ethics committees? What certification or conformity requirements should apply? How ought general-purpose AI systems be governed in research contexts? And, importantly, what types of assessments – beyond purely technical validation – are necessary before these tools can be responsibly implemented in practice?

These uncertainties are not merely technical gaps; they reflect a familiar pattern in the history of clinical research governance. Regulatory frameworks have often evolved reactively, shaped by events that exposed weaknesses in oversight – for example the thalidomide tragedy, the Tuskegee syphilis study, and more recent medical device scandals (e.g. Poly Implant Prothèse breast implants and metal-on-metal hip implants) that contributed to the development of the European Union's Medical Device Regulation (MDR). The uncomfortable question, therefore, is whether we are prepared to address foreseeable risks proactively, or whether we will once again wait for failure to force reform.

At the same time, a precautionary approach must not slide into overregulation, which could stifle innovation. A balanced approach is essential. Hard law should not be overly detailed or prescriptive but instead set broad principles and general obligations, while operational detail should be developed through soft law instruments such as professional guidelines and institutional policies. Such guidelines should include structured risk-evaluation frameworks and concrete guidance on how abstract ethical principles can be translated into everyday trial workflows.

Ultimately, effective governance depends not only on rules but on competence. Building AI literacy among researchers, ethics committees, and regulators is therefore essential to enable meaningful evaluation and responsible implementation.

Interdisciplinary collaboration

True progress does not arise from diluted expertise. It emerges from strong, well-grounded disciplinary knowledge combined with openness and a willingness to understand other perspectives.

Ethical acceptability cannot be assumed to be uniform across stakeholders. What appears acceptable to developers or sponsors may raise concerns among patients, clinical researchers, or ethics committees. Ethical norms must therefore be negotiated through inclusive dialogue.

Conclusion

AI will continue to shape clinical trial management. Its potential is significant, and so are its risks. Responsibly integrating AI into trial processes requires more than good intentions or nominal oversight. It demands robust governance structures, systematic AI literacy, sustained trust-building, and continual ethical reflection. The conversation about AI in clinical research must remain ongoing and evolve alongside technological progress and shifts in societal expectations. In the end, AI should not be viewed as a stand-alone innovation. It should be understood as part of a broader transformation of clinical research, one that must be shaped deliberately to remain ethical.

References

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