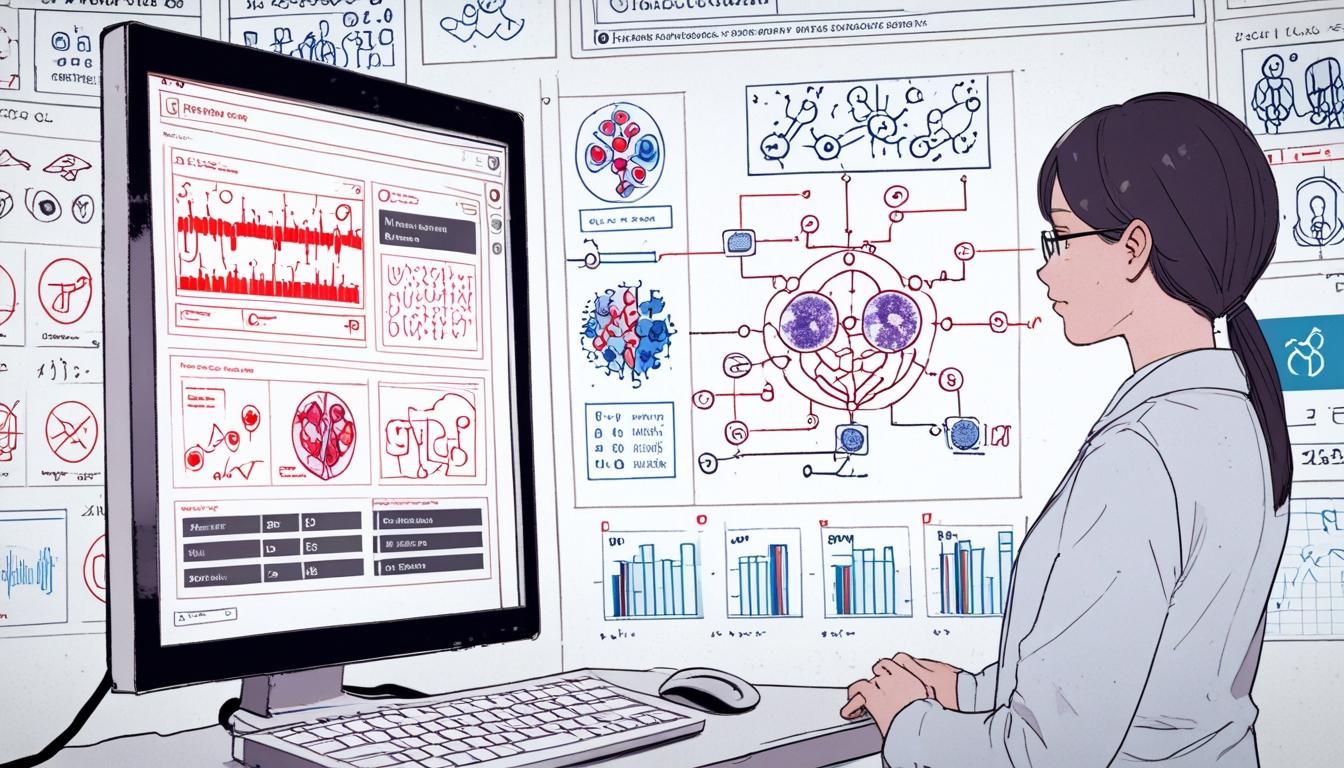
# AI integration revolutionises clinical trials amid complex regulatory landscape



Artificial intelligence (AI) technologies are increasingly being integrated into clinical trials, offering new possibilities for improving trial efficiency, patient accessibility, and data quality. This development is occurring within a context of evolving regulatory frameworks at the state, federal, and international levels, which clinical investigators must navigate carefully to ensure compliance and address associated risks.

AI methodologies such as machine learning, deep learning, natural language processing, computer vision, and generative AI are currently employed to assist with various aspects of clinical trials. According to the US Food and Drug Administration (FDA), these technologies have been used to infer drug safety and efficacy, optimise trial design and efficiency, and extract relevant information from electronic health records to identify prospective trial participants. AI tools have become particularly significant in decentralised clinical trials (DCTs) and the use of digital health technologies (DHTs), which increase trial accessibility by enabling remote patient engagement through telemedicine, wearable devices, and continuous monitoring without requiring frequent visits to trial sites.

These AI-driven approaches can facilitate real-time collection and analysis of patient data, helping researchers monitor health and protocol adherence more efficiently. This integration has expanded the reach of clinical trials, reduced participant burden, and accelerated trial completion timelines while maintaining data integrity.

However, the growing reliance on AI raises new challenges for clinical investigators, particularly regarding regulatory compliance and liability issues. Investigators operating without sufficient support infrastructure may increasingly depend on AI-enabled tools to manage trial operations, analyse large datasets, improve diagnostic accuracy, and automate routine tasks. The safety, transparency, and effectiveness of these AI systems must be ensured, but the lack of uniform medical data standards and interoperability remains an obstacle.

At the state level in the US, several jurisdictions have introduced or enacted legislation affecting AI use in healthcare. For example, California’s Artificial Intelligence in Healthcare Services Bill (AB 3030) requires that AI-generated communications containing patient clinical information include disclaimers and instructions for contacting human healthcare providers. Colorado’s Consumer Protections for Artificial Intelligence (SB24-205) establishes a framework regulating high-risk AI applications, which may include those used in clinical trials. Utah’s Artificial Intelligence Policy Act mandates disclosures when consumers interact with AI systems in regulated professions, including healthcare.

The FDA at the federal level has issued draft guidance (expected in January 2025) outlining considerations for AI tools used throughout the drug product lifecycle. The guidance proposes a risk-based credibility assessment framework for AI models that support regulatory decisions about drug safety, effectiveness, and quality. However, federal regulations remain subject to ongoing developments and adaptations.

Internationally, the World Health Organization released guidelines on the ethics and governance of AI in health care in January 2024. The European Union's Artificial Intelligence Act (EU AI Act) is a particularly significant regulation, classifying AI applications according to risk levels and mandating transparency around their use. The Act bans AI uses deemed to present unacceptable risk and sets specific requirements for high-risk healthcare-related AI, potentially affecting clinical trial software tools. Researchers and sponsors must assess whether deployed AI is high or low risk and maintain transparency about AI involvement in trials.

Clinical investigators also must comply with data protection laws such as the Health Insurance Portability and Accountability Act (HIPAA) in the US and the General Data Protection Regulation (GDPR) in Europe. Handling large volumes of clinical trial data creates vulnerabilities to data breaches and unauthorised access. Investigators are encouraged to implement robust data security measures, including comprehensive breach response plans and collaboration with AI providers to allocate responsibilities clearly. Regular testing of these plans is advised to mitigate risk.

Additionally, investigators must understand the nature of data collected, including whether it constitutes protected health information (PHI), and the implications of anonymisation efforts. Despite anonymisation, risks of data re-identification persist and may result in liability. Effective data governance frameworks and transparent communication with participants regarding data use are important components of risk management.

The Clinical Leader is reporting that the integration of AI in clinical trials represents a significant shift in the research environment, facilitating decentralised and technologically enhanced trials but also introducing complex regulatory and operational challenges. A follow-up article is planned that will provide guidance for clinical investigators on implementing AI governance systems, overseeing AI use responsibly, securing informed consent, and fostering collaboration with AI technology providers. This upcoming guidance aims to assist investigators in effectively managing the evolving AI landscape in clinical research.

Source: [Noah Wire Services](https://www.noahwire.com)

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