

# AI in clinical trials: Current status, challenges, and future directions for emergency infectious disease clinical trials — Insights from the 2025 iCROWN Symposium

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**Abstract:** Artificial intelligence (AI) has the potential to transform how drug development and clinical trials are conducted. The 2025 Infectious Disease Clinical Research Network with National Repository (iCROWN) Symposium held in Japan on January 26, 2026 brought together experts from academia, industry, and research ethics to discuss current applications, limitations, and ethical considerations of AI in clinical trials, with a particular focus on emergency infectious disease research. Presentations highlighted a wide range of use cases for generative AI, including protocol writing; generating and reviewing clinical trial documents such as the statistical analysis plan (SAP) and the clinical study report (CSR); patient matching; data monitoring; and query creation. These applications are expected to accelerate and streamline clinical trials while maintaining quality and reducing costs. Standardization of digital data flows in clinical trials further facilitates the adoption of AI. Drawing on the FDA–EMA guiding principles for good AI practice, discussions emphasized the importance of accountability, explainability, fairness, and generalizability, while addressing risks such as overreliance, bias, and deskilling. The symposium concluded that while AI may enable more efficient clinical trial deployment during future public health crises, its challenges must be recognized and addressed.

**Keywords:** clinical trials, artificial intelligence, infectious diseases

The rapid advancement of artificial intelligence (AI) technology is transforming every stage of clinical research, including protocol writing, subject selection, data analysis, and safety assessment (1,2). Within this context, the 2025 Infectious Disease Clinical Research Network with National Repository (iCROWN) Symposium held in Japan on January 26, 2026 featured presentations and lively discussions on the current status and future prospects of AI utilization in clinical trials. Participants from academia, pharmaceutical companies, and research ethics experts shared the latest insights and case studies (Figure 1). The symposium explored how AI (including machine learning and generative AI) can streamline clinical trials while also addressing its limitations and challenges.

From an academic perspective, generative AI use cases included automated generation of the statistical analysis plan (SAP) and the clinical study report (CSR) based on study protocols; matching patients to trials and vice versa. Trends toward international standardization of study protocols (3) and Digital Data Flow (4) were explained. Pharmaceutical companies also use AI to generate various trial-related documents from study protocols automatically or to review them. Efforts are underway to explore how AI can be applied to streamline

data monitoring, such as automatically generating queries for data in electronic data capture (EDC) systems, and to enhance quality control in clinical trials.

Furthermore, until approximately 2021, ethical debates surrounding healthcare-related AI primarily focused on the collection and use of personal information for purposes such as diagnostic support. In recent years, however, these discussions have significantly expanded to include clinical trials and research activities. The difficulty in discussing AI ethics in healthcare stems from factors such as the diversity of people's visions of AI and the different roles of professionals and patients. Centered on the ten principles outlined in the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) joint statement on AI in drug development, "Guiding Principles of Good AI Practice in Drug Development" (2), presentations at this symposium highlighted key considerations for the use of AI in drug development, including the appropriateness of judgment, decision-making and responsibility, explainability, and the need to ensure generalizability and fairness. It also addressed potential issues arising from over-reliance on AI, including deskilling (erosion of professional judgment) (5), diminished accountability, biased training



**Figure 1. Photo of the symposium venue.** The symposium was held on January 26, 2026, at the JIHS Reception Room, Tokyo. Three invited speakers and five panelists discussed the use of AI in clinical trials.

data, and possible degradation of AI performance (2).

The World Medical Association (WMA) and the American Medical Association (AMA) refer to AI as augmented intelligence rather than artificial intelligence, and educational settings face the urgent need to reevaluate learning assessment methods. Appropriate AI use requires responsible collaboration with AI, including the ability to critically evaluate AI outputs, procedures for managing system failures, and protocols for responding to incidents arising from AI use.

A key feature of this symposium was the sharing of the latest insights on AI use in clinical trials from academic, industry, and research ethics perspectives, followed by discussions on how we could apply them to infectious disease clinical trials during emergencies. While there is no doubt that AI will advance the streamlining and acceleration of clinical trials and drug development, the panelists re-emphasized that we must recognize its limitations and challenges. To ensure appropriate use during emergencies, it is also essential to implement AI in clinical trials during peacetime and to accumulate practical experience.

iCROWN will continue to closely monitor new trends in clinical trials and drug development in the AI era. While noting both the advantages and challenges, we will explore the future direction of clinical trials for the next pandemic.

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