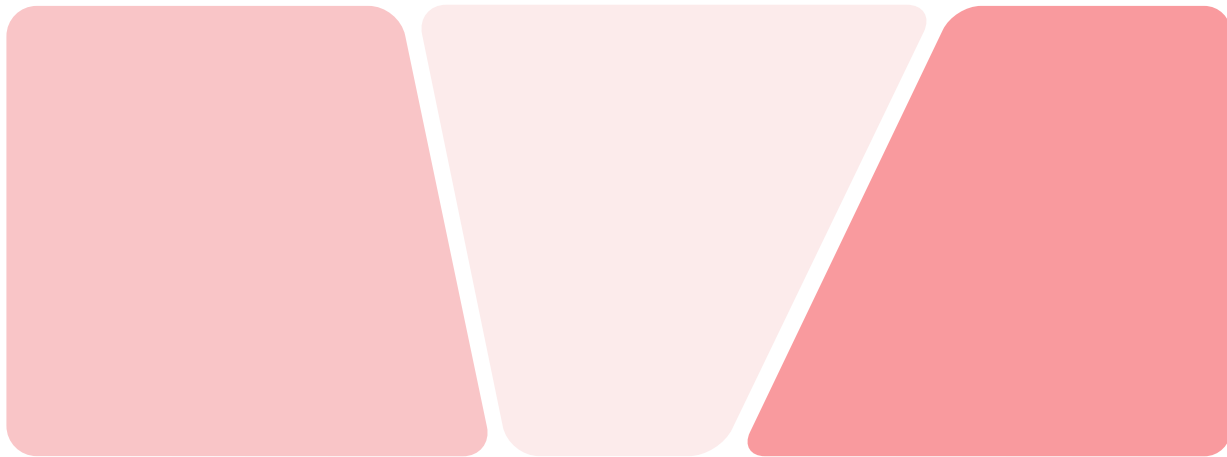


Editorial



Exploring new territory: Various perspectives on AI in clinical research and its impact on the regulatory landscape

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Artificial intelligence (**AI**) is influencing clinical research in multiple interconnected ways. It has the potential to address long-standing challenges across the clinical research ecosystem by improving efficiency, supporting decision-making, and enabling new approaches throughout the clinical research process. At the same time, clinical research plays an important role in generating the data and evidence needed to develop, validate, and evaluate AI-enabled medical technologies and to establish whether they are sufficiently safe, reliable, and effective for their intended use. AI is also reshaping the regulatory landscape as a technology that requires oversight. These interactions between AI, clinical research, and the regulatory landscape are unfolding within an environment that must respond to fast-moving technologies while maintaining established standards for research quality and participant protection.

This eleventh issue of *Regulatory Affairs Watch* explores these interactions, focusing primarily on

how AI may help address challenges in clinical research and on the evolving regulatory landscape surrounding its use. A complementary perspective on the clinical evidence needed to bring AI-enabled medical technologies into practice is provided in a case study.

Deep Dive

Clinical research is becoming increasingly complex, costly, and data-intensive. Whether AI can address these issues, and under what conditions, is the question behind our Deep Dive article, co-authored with Fanny Muet. The article approaches the topic from two complementary angles: The first part looks at AI tools for researchers and explores how AI may contribute to different domains across the clinical research ecosystem while also considering the limitations and conditions associated with their use. The second Regulatory Spotlight section turns

to regulatory frameworks and examines the EU's Artificial Intelligence Act, which is currently the most detailed legislation of its kind and whose scope extends beyond the EU.

Feedback From

As AI becomes increasingly embedded in clinical research and health care, regulators and ethics bodies are confronted with questions that cut across existing frameworks and responsibilities. Our Feedback From articles bring the perspectives of two key Swiss authorities directly into the discussion on AI in clinical research.

Swissmedic: In our first Feedback From article, Einat Albers-Schönberg from Swissmedic provides the regulatory authority's perspective on using AI in medical devices.

swissethics: In our second Feedback From article, Pietro Gervasoni from swissethics considers ethical challenges related to AI.

Views and Opinions

Using AI in clinical research touches research practice, data governance, law, patient involvement, and clinical trial management. Moreover, certain AI use cases, such as large language models, are opening further areas of exploration. This issue of *RA Watch* brings together several perspectives from across the clinical research community.

SCTO perspective: The SCTO is actively following developments at the intersection of AI and clinical research and is exploring how the clinical research community can engage with the opportunities and challenges these developments bring. As part of these efforts, it has established a new project group on AI in clinical research that is led by Anastasios Stathis. He introduces the project and shares his perspective on the topic in an exclusive Q&A for our Views and Opinions section.

Legal perspective: The growing capabilities of AI bring complex legal and regulatory questions

for clinical research. Audrey Lebret discusses the implications of AI for fundamental human rights and how its use may challenge established concepts of data protection, consent, and non-discrimination. She also considers how, without appropriate safeguards, AI systems may reproduce existing biases or give rise to new forms of discrimination.

Patient perspective: The increasing use of AI in clinical research also raises the question of how patients and the public should be involved in its development and use. In our third Views and Opinions contribution, Christine Jacob from the European Patients' Academy on Therapeutic Innovation Switzerland (**EUPATI CH**) takes a closer look at patient and public involvement in relation to AI and how AI technologies could deliver meaningful and trustworthy value in real-world research settings.

Clinical trial management: AI has the potential to support clinical trial management, from evaluating trial feasibility and supporting patient recruitment to assessing trial progress and outcomes. Lara Bernasconi discusses the use of AI systems in clinical trial management while also considering ethical blind spots, trade-offs, and the need for interdisciplinary collaboration to accompany their integration into clinical research.

Large language models: Large Language models (**LLMs**) are rapidly entering clinical research, with possible applications ranging from evidence synthesis and protocol development to data extraction. Benjamin Ineichen examines both the potential of these tools and an important limitation concerning the performance evaluation of them. In his article, he also highlights the gap between the possible capabilities of LLMs and their demonstrated clinical value.

Case Study

AI-enabled medical technologies also depend on clinical research: they require robust clinical evidence before they can be introduced into clinical practice. Our Case Study section provides a concrete example through QUMEA, an AI-enabled, radar-based technology for contactless patient monitoring. Cyrill

Gyger and Jonas Reber show how the architecture of the sensor and the system shaped the technology's use of AI, how the company approached privacy and data protection, and what regulatory pathway the product took. The case study illustrates clinical research's essential role not only as a field in which AI can be applied but also as part of the pathway through which AI-enabled medical technologies can demonstrate their performance and thus ultimately reach clinical practice.

AI is developing at a remarkable pace, and its implications for clinical research are only beginning to unfold. At this stage, there may be more questions than answers, and many of the questions raised in this issue will continue to evolve alongside the technology itself. Rather than serving as the final word in this discussion, we hope this issue contributes to an open dialogue between stakeholders. The SCTO Regulatory Affairs Platform will continue to follow these developments, explore their implications for clinical research, and create opportunities for discourse throughout the clinical research community.

We would like to warmly thank all the experts who contributed their knowledge and perspectives to this issue, and we hope you enjoy reading this eleventh issue of *Regulatory Affairs Watch*.

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