

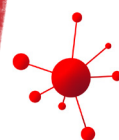
REGULATORY AFFAIRS WATCH

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Artificial intelligence in clinical research



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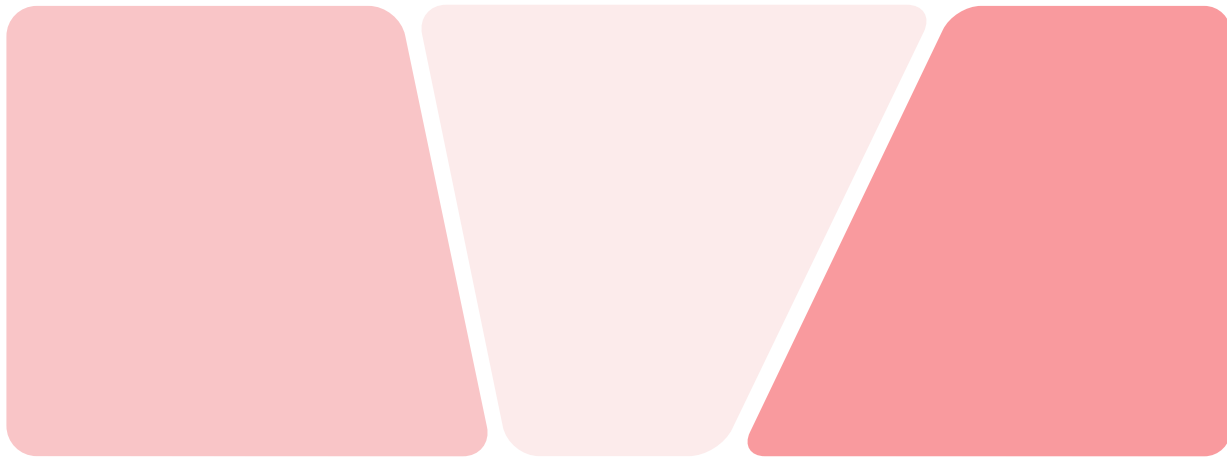
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Cover illustration: A kite is guided by a human hand, yet its path is shaped by the changing wind. In much the same way, AI in research is guided by human oversight, while its outputs are shaped by data, context, and application. This single-line illustration was designed by Aliénor Held for *Regulatory Affairs Watch Issue 11*.

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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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Deep Dive



AI in action in clinical research: Applications, limitations, and the emerging regulatory framework

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Artificial intelligence (**AI**) is influencing clinical research in many interconnected ways. It has the potential to address long-standing challenges throughout the research process by improving efficiency, supporting decision-making, and enabling new research methodologies. At the same time, clinical research generates the data and evidence needed to develop, validate, and evaluate AI-enabled technologies before they can be used in clinical practice. AI is also reshaping the regulatory landscape, both as a technology requiring appropriate regulatory oversight and as a tool that regulatory authorities may use in their own activities. This Deep Dive article focuses primarily on how AI may help address challenges facing clinical research by illustrating how it can be applied throughout the clinical research ecosystem. The article then looks beyond clinical research to explore the evolving role of AI in the broader regulatory landscape. A dedicated **Regulatory Spotlight** section provides a concise overview of the European Union's Artificial Intelligence Act and its implications for AI-enabled medical devices.

Challenges facing clinical research

As clinical research becomes increasingly complex, costly, and data-intensive, improving the research process itself has become an important area of investigation. The recurring patterns that emerge from such investigations reveal that many challenges in clinical research are systemic rather than study-specific.

Within clinical research, clinical trials remain one of the most resource-intensive and operationally challenging settings. Large analyses of clinical trials consistently identify participant recruitment, protocol complexity, prolonged study timelines, feasibility constraints, high costs, and premature trial discontinuation as persistent barriers that undermine both trial efficiency and scientific yield. For example, a machine learning analysis of over 16,000 trials found that protocol complexity has risen substantially over the past decade, correlating with longer trial duration.¹ A separate, systematic review of 347 randomised trials across the UK, Switzerland, Germany, and Canada found that 31.1% of the trials were discontinued, predominately due to poor recruitment.² A similar pattern was found in surgical trials: in a study of more than 2,500 randomised surgical trials, fewer than one in five were finished on time, and almost 20% were stopped early due to an insufficient number of participants.³

These challenges highlight opportunities for improving how clinical research is designed, conducted, and managed. And because these challenges are not isolated to individual studies but reoccur across trials, settings, and countries, addressing them at the level of the research process itself has become an important objective in its own right.

One resource that can be used to address these challenges is artificial intelligence (**AI**). Because AI tools can be used across many studies, they may help solve these problems more broadly and thus reduce the need to find a different fix for each trial. Researchers are starting to conduct studies that look at how much efficiency AI can bring to clinical trials, for example in the

areas of recruitment and retention, and that examine whether AI can reduce costs and increase patient satisfaction.⁴ The following sections illustrate how AI is increasingly being explored across four different domains of the clinical research ecosystem in order to address some of the challenges facing clinical research.

Using AI to address challenges across the clinical research ecosystem: Examples from four domains

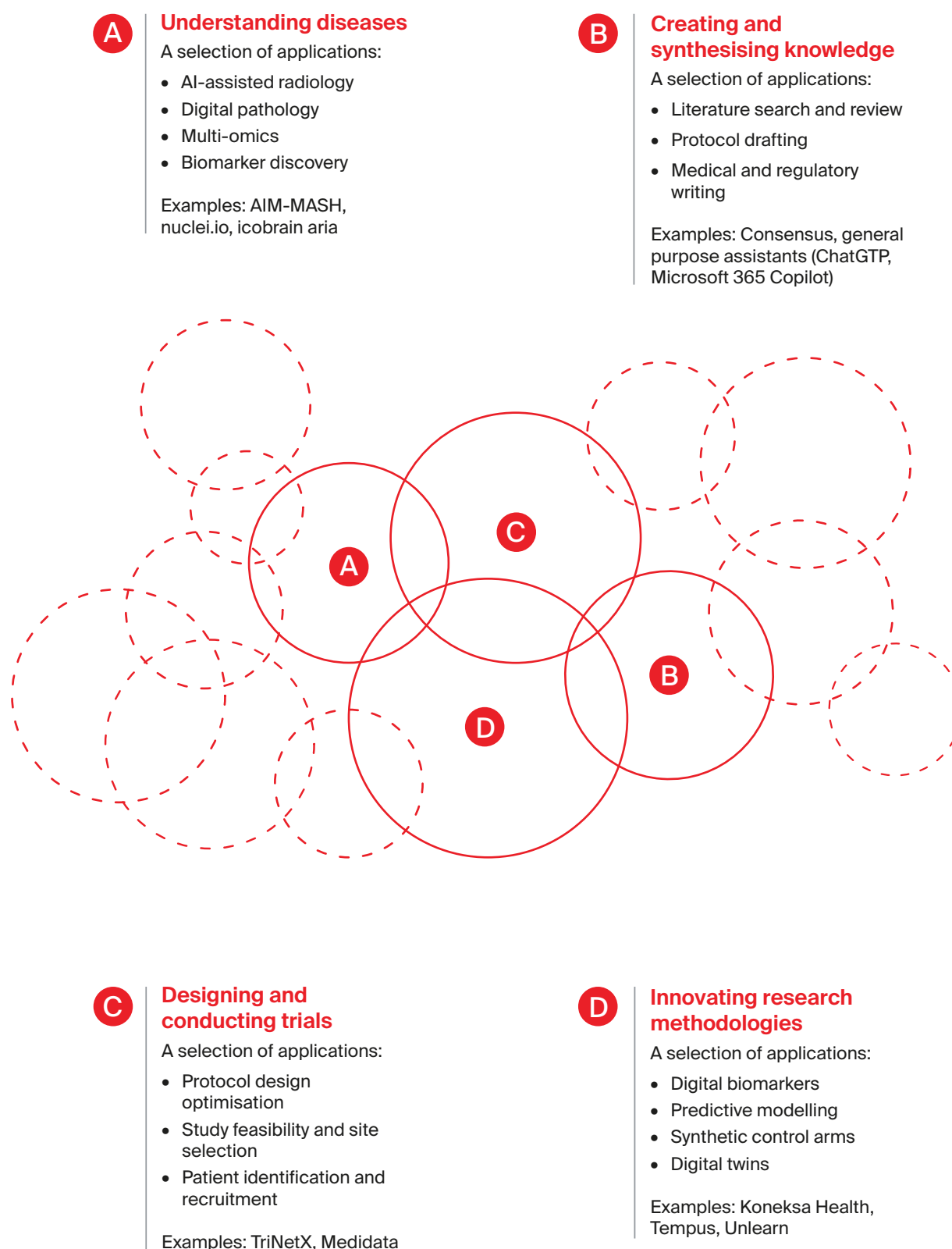
AI applications range from understanding disease biology and supporting trial operations to analysing complex data outputs and facilitating regulatory activities. This section explores applications in the following four domains: understanding diseases, creating and synthesising knowledge, designing and conducting trials, and innovating research methodologies. **Figure 1** provides examples of how AI is being used within these four domains, although the maturity, real-world adaptability, and adoption of the specific applications may vary.^A Furthermore, the domains are interconnected rather than sequential, and advances in one domain may support progress in another. And while some applications are already well established (e.g. AI-assisted radiology and digital pathology), others are still being evaluated for their methodological and/or regulatory feasibility (e.g. digital twins and synthetic control arms).

Domain A: Understanding diseases

Among all AI applications currently being used in health care and clinical research, some of the most mature ones are AI-assisted radiology and digital pathology applications. Once radiological images and pathology slides are digitised, AI algorithms can be used to detect and quantify features such as cell types, tissue structures, or disease markers at a scale and consistency that would be difficult to achieve with visual human assessment. This reduces both the time required for review and the inter-observer variability between different specialists. Using AI in this field can support disease characterisation, patient stratification, and biomarker discovery.^{5,6}

^A The tools named in the figure are used for illustrative purposes only and do not imply any endorsement, recommendation, or assessment of their performance or regulatory status by either the authors or the Swiss Clinical Trial Organisation (**SCTO**).

Figure 1: Examples of how AI is being applied within selected domains of the clinical research ecosystem



Besides processing images, AI can also combine multi-omics data such as genomics, transcriptomics, and proteomics with imaging-based data. This has shown promise in areas such as precision cancer diagnosis and prognosis.^{7,8}

AI-enabled research methodologies are beginning to enter formal regulatory evaluation. One example of regulatory maturity within the domain of understanding diseases is the AI-based measurement of metabolic dysfunction-associated steatohepatitis (**AIM-MASH**) tool. This AI-powered pathology methodology is used for scoring liver biopsies in metabolic dysfunction-associated steatohepatitis (**MASH**) clinical trials.⁹ In 2025, the European Medicines Agency (**EMA**) issued a qualification opinion^{B,C} for its defined context of use that supported its application in future MASH drug development.¹⁰

Domain B: Creating and synthesising knowledge

This domain focuses on how AI supports the creation, synthesis, and communication of knowledge across the clinical research ecosystem. The AI tools in this domain are generally built on large language models (**LLMs**) that are trained on large amounts of text in order to generate and process natural language. These tools can review scientific literature, clinical guidelines, and regulatory documents in order to produce a summary or to answer or draft scientific and regulatory documents.¹¹ These AI-supported capabilities have the potential to improve efficiency and consistency while reducing administrative burden, thus allowing researchers to focus more on scientific interpretation and decision-making. However, independent evaluations of LLMs' real-world performance remain limited to date.¹² As with all AI applications in clinical research, human oversight remains essential, and outputs require critical reading and verification, particularly in regulated research environments.

Unlike AI software intended to directly benefit individual patients or support treatment decisions, these AI-supported knowledge synthesis tools are not usually

considered medical device software under the EU's Medical Device Regulation (**MDR**) as long as they do not claim a medical purpose (MDR, Article 2(1); MDCG 2019-11 Rev1). Therefore, they generally fall outside of the MDR and are not subject to its clinical evaluation or conformity assessment requirements. However, regardless of their MDR status and depending on how they are used, AI-supported tools may be subject to requirements under the EU's Artificial Intelligence Act (**AI Act**) (e.g. transparency requirements concerning certain AI-generated content) and to data protection legislation such as the EU's General Data Protection Regulation (**GDPR**) and Switzerland's Data Protection Act (**FADP**) (e.g. if an AI-supported tool is used to process documents containing identifiable patient information).

Domain C: Designing and conducting trials

Clinical trial operations remain one of the most challenging aspects of clinical research and, consequently, one of the most promising domains for AI applications. Researchers are increasingly exploring how AI could support different aspects of trial planning and conduct, including protocol optimisation, study feasibility, site selection, participant recruitment, and the identification of data anomalies or unusual patterns that require further investigation while a trial is being conducted.^{13,14}

Patient recruitment constitutes one of the most critical bottlenecks in clinical trials. AI can significantly support this phase by automating the screening of electronic health records and matching patients to complex eligibility criteria potentially more rapidly than manual processes. AI models can also be used to optimise site selection by analysing historical site performance, patient availability, and geographic factors. Together, these approaches may improve recruitment rates, reduce screening failures, and enhance overall trial efficiency.

While several commercial solutions have emerged in this domain, routine implementation remains limited

^B EMA qualification is a voluntary procedure in which the Committee for Medicinal Products for Human Use (**CHMP**) issues an opinion on whether a method is acceptable for a specific use in medicine development that is tied to a defined context of use. A qualification opinion concerns the method rather than a medicinal product, and it is not a marketing authorisation.

^C The tool is now called AIM-MASH AI Assist; the EMA opinion retains the earlier AIM-NASH name because the qualification was filed before the revised MASH nomenclature was accepted.

and heterogeneous across organisations and research settings. Trial design and conduct therefore represents an area of active innovation rather than established clinical research practice.¹⁵

Regulators are taking an active interest in understanding how AI could improve clinical trial operations. For example, in April 2026 the US Food and Drug Administration (**FDA**) issued a request for information on the proposed AI-Enabled Optimization of Early-Phase Clinical Trials pilot programme, seeking input on how AI-enabled technologies could improve the efficiency, speed, and quality of decision-making in early-phase trials.¹⁶

Domain D: Innovating research methodologies

Generating robust clinical evidence on the safety and efficacy of interventions is the ultimate goal of clinical trials. AI is being increasingly explored to support how evidence is generated, analysed, and interpreted. Current developments in this domain include digital biomarkers (i.e. objectively quantifiable indicators of biological processes or responses to treatments or to interventions, measured using digital technologies), predictive modelling, synthetic control arms, and digital twins, among others.¹⁷

The increasing adoption of digital health technologies (**DHTs**) and decentralised clinical trials (**DCTs**) has driven wider use of wearable devices that continuously monitor patients outside the clinic and track signals such as heart rate, movement, or sleep instead of relying on occasional site visits. AI-based algorithms then convert this continuously collected data into digital biomarkers that are clinically meaningful, standardised measurements that can complement or substitute endpoints.¹⁸

AI is also being used for predictive modelling, which looks at clinical and real-world data together to predict how a disease might progress, how a patient might respond to treatment, or other outcomes of a trial. A more recently developed methodology is the synthetic control arm, in which researchers use existing external data to build a comparison group instead of enrolling a separate group of patients to receive a placebo or standard of care. Another application is a digital twin, where a virtual version of a specific patient is created to simulate how they might have progressed without

treatment. In practice, this could mean fewer patients need to be enrolled, thus reducing the exposure to a placebo or to a less effective comparator and making trials more feasible, particularly for rare diseases where the eligible population is small. These methods are still at different stages of scientific and regulatory maturity, but they point to how AI could gradually change the way clinical evidence is generated.¹⁹

Some research methodologies have already entered formal regulatory evaluation. One example is Prognostic Covariate Adjustment (**PROCVA**), a methodology developed by Unlearn that received an EMA qualification opinion in 2022 for use in phase 2 and phase 3 trials with continuous outcomes. By incorporating AI-derived prognostic predictions based on patients' baseline characteristics into the statistical analysis of randomised clinical trials, it has been shown to improve the precision of treatment effect estimates.²⁰

It is important to keep in mind that these four domains should not be viewed as independent applications or sequential stages of clinical research. Advances in one domain generate new data, knowledge, and evidence that strengthen the other domains. Improved disease understanding informs better trial design; more efficient trials generate higher-quality evidence; and newly generated evidence contributes to refining scientific knowledge while supporting the development and validation of future AI applications. In this way, AI is progressively becoming embedded within a continuous learning ecosystem, where advances in both clinical research and AI reinforce one another.

AI beyond clinical research

AI can be applied across a range of areas related to clinical research and drug development. One of the most active application fields is pharmacovigilance, where AI is being explored to support case processing, literature screening, signal detection, safety surveillance, and benefit-risk assessment. In its recent report [Artificial Intelligence in Pharmacovigilance](#), the Council for International Organizations of Medical Sciences (**CIOMS**) Working Group XIV concludes that AI has considerable potential to improve pharmacovigilance activities by increasing efficiency and consistency.

At the same time, it emphasises that AI should augment rather than replace human expertise and that its implementation requires appropriate validation, transparency, governance, and human oversight.²¹

Regulatory authorities are also beginning to adopt AI in selected activities. The European Medicines Agency (**EMA**) and the Heads of Medicines Agencies (**HMA**) jointly adopted one of the most structured approaches in their [Data and AI in Medicines Regulation](#) workplan, which covers activities from 2026 to 2028. By providing guidance, opportunities for collaboration and experimentation, and access to AI-enabled tools, the workplan promotes the responsible use of AI across the European medicines regulatory network. The EMA has also introduced [Scientific Explorer](#), an AI-assisted search tool that helps assessors quickly retrieve relevant scientific advice, assessment reports, and previous regulatory information but leaves scientific judgement to the assessor. In the United States, the FDA has also started integrating AI into its internal workflows through [Elsa](#), a generative AI assistant designed to support activities such as scientific review and document analysis.

Future perspectives

Artificial intelligence holds significant potential to support researchers throughout the clinical trial life cycle: from study design and patient recruitment to data analysis and operational monitoring. By enabling more efficient use of data, improving patient matching, and supporting real-time decision-making, AI may contribute to addressing some of the long-standing inefficiencies that have historically limited trial performance. In fact, AI is already being applied throughout many stages of clinical research, and its use is expected to continue expanding. At the same time, how AI is implemented – i.e. how it is validated, governed and integrated into existing workflows – is receiving increasing attention.

AI's integration into clinical research cannot be considered purely as a technological enhancement. The use of AI introduces new operational, ethical, and compliance challenges. In addition to the regulatory and technical considerations, the deployment of AI systems can also be resource-intensive, requiring

specialised expertise for development and validation as well as significant effort and cost to ensure verification, regulatory compliance, and ongoing performance monitoring. The successful implementation of AI tools requires robust data governance, data protection, data security, transparency, and continuous oversight, which may fundamentally reshape how clinical trials are designed, conducted, and evaluated.

Another emerging consideration is the environmental impact of AI, which is becoming an increasingly important dimension of its future governance. The development, training, and deployment of increasingly complex AI models require substantial computational resources and energy consumption. In the context of growing efforts to reduce the environmental footprint of health care and research activities, future policies may increasingly consider the sustainability of AI systems alongside their performance and safety. This could lead to the emergence of new expectations regarding resource efficiency, model optimisation, and the responsible use of AI technologies.

Conclusion

Several use cases of AI applications in clinical research already exist, with many more on the horizon. However, understanding where AI can deliver the greatest value also requires identifying the major operational challenges that continue to limit the efficiency, quality, and success of clinical trials. Moreover, AI should not be viewed as a replacement for research and clinical expertise but rather as a complementary tool that can enhance human capabilities. Its long-term value will depend on achieving a careful balance between innovation, regulatory compliance, ethical responsibility, and the resources these systems consume. Maintaining this balance will ensure that advances in AI translate into meaningful improvements in trial efficiency, scientific validity, and patient outcomes.

Regulatory Spotlight

AI regulation is developing differently across jurisdictions. The European Union has introduced the Artificial Intelligence Act (AI Act) as a broad, horizontal, and risk-based framework. Switzerland has not opted for a comparable horizontal law, and the Federal Council confirmed in February 2025 that AI will continue to be regulated through existing sectoral legislation and targeted amendments where needed. In March 2025, Switzerland signed the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law, the first legally binding international treaty in this field. Switzerland intends to implement the Convention through amendments to existing law, sector-specific measures where needed, and non-binding measures such as standards, industry solutions, and voluntary commitments.²² Draft legislation implementing the Convention in Swiss law is expected by the end of 2026. The EU has also signed the Convention, which it implements through its AI Act.

A closer look at the AI Act

The EU's AI Act currently provides the most developed horizontal legal framework for AI and has important implications for AI-enabled medical devices and other healthcare applications. It is the first legal framework adopted at the EU level to regulate the development, marketing, and use of artificial intelligence systems. Initially proposed by the European Commission in April 2021, it was formally adopted in 2024, with phased implementation running to 2028 depending on the specific provisions.

This regulation reflects an effort to balance technological innovation with the protection of fundamental rights, safety, and public health. Unlike sector-specific regulations, the AI Act follows a cross-sectoral approach that applies

broadly across the fields where AI systems are developed or deployed. Certain activities are nonetheless excluded: the regulation does not apply to any research, testing, or development activity related to AI systems or AI models prior to them being placed on the market or put into service. It also does not apply to systems developed and put into service for the sole purpose of scientific research. The regulation's wording is not always clear, which has made it difficult to apply in practice and has led to calls for clearer definitions and guidance.²³

A risk-based approach

The AI Act classifies artificial intelligence systems according to their risk and potential level of harm. It distinguishes the following four main categories:

- **Unacceptable-risk systems** (e.g. systems involving certain types of behavioural manipulation or social scoring) are prohibited.
- **High-risk systems** (e.g. AI systems used in recruitment processes or credit scoring as well as AI systems that are medical devices) are subject to strict requirements both before and after being placed on the market.
- **Limited-risk systems** (e.g. chatbots) must comply with specific transparency obligations.
- **Minimal-risk systems** (i.e. most AI applications that do not fall into the categories above, such as spam filtering or basic recommendation systems) may generally be used freely with few obligations under the AI Act.

This tiered approach makes it possible to tailor regulatory requirements to the potential impact of each system on individuals and society.

Requirements for high-risk systems

AI systems used in clinical research may fall into the high-risk category depending on their intended purpose and applicable regulatory classification, particularly when they are incorporated into regulated medical devices (e.g. certain AI-based diagnostic imaging or pathology software). Such high-risk systems will be subject to a set of harmonised requirements at the EU level. When AI systems used in critical contexts (such as health care and clinical trials in particular) are considered high-risk, they require the following in particular:

- the implementation of a risk management system covering an AI system's entire life cycle
- robust data governance and quality standards for training, validation, and testing datasets
- the preparation of comprehensive technical documentation demonstrating regulatory compliance
- transparency obligations and, to some extent, requirements related to explainability
- post-market monitoring measures, including performance tracking and incident management.

The goal of these requirements is to ensure that high-risk AI systems achieve a high level of safety, reliability, and robustness while remaining controllable by human users.

Scope and applicability

The AI Act applies not only to entities established within the EU but also to organisations located outside the EU whose AI systems are sold on the European market or used within it. Therefore, the regulation has significant influence beyond the EU's borders and encourages international actors to align their practices with its requirements in order to ensure access to the European market.

The interplay between AI regulation and medical device legislation

The interplay between the EU's AI Act and its Medical Device Regulation (MDR) is particularly significant, as many AI-based systems used in health care fall under multiple regulatory regimes. Frameworks such as the AI Act introduce risk-based requirements for AI systems, particularly for those in high-stakes areas like health care. For AI-based medical devices, these requirements are in addition to obligations in existing legislation, thus further increasing regulatory and operational complexity in clinical research. At the EU level, when software incorporating AI is intended for medical purposes – such as the diagnosis, prevention, monitoring, prediction, or treatment of a disease – it may be classified as medical device software (**MDSW**) under the MDR. It is important to emphasise that the use of AI alone is not a determining factor for medical device classification. The assessment is based solely on the intended purpose of the software. As a result, the same algorithm may be considered a medical device in a clinical context but not when used for general wellness or non-medical applications.

How the MDR and AI Act interact

When an AI system is classified as a medical device, it becomes subject to two regulatory regimes simultaneously:

- the EU's MDR, which governs the safety, clinical performance, and classification of medical devices
- the EU's AI Act, which sets specific requirements for high-risk AI systems.

This results in a layered regulatory structure rather than the replacement of one framework by another. The AI Act does not supersede the MDR; instead, it complements it by introducing additional requirements that are specific to AI.

Implications for compliance and regulatory convergence

A key point is that medical devices incorporating artificial intelligence may be classified as high-risk systems under the EU's AI Act, depending on their intended purpose and whether they require third-party conformity assessment under the MDR or the In Vitro Diagnostic Medical Devices Regulation (IVDR) (see AI Act, Article 6(1) and Annex I). This implies that such systems must comply not only with applicable requirements of the MDR or IVDR (including CE conformity marking, conformity assessment, and clinical evidence) but also with the additional obligations applicable to high-risk AI systems described above. This dual regulatory oversight reflects a broader shift towards a convergence of frameworks governing digital health technologies. While the MDR establishes a product-centred approach focused on the medical device itself, the AI Act introduces a complementary perspective centred on the behaviour of algorithmic systems and their dynamic life cycles.

This overlapping structure raises important challenges for manufacturers, particularly in relation to the following issues:

- the consistency of compliance requirements across frameworks
- the cumulative regulatory burden
- the integration of quality management systems
- the life cycle management of software and updates to AI models.

In this context, an analysis of the implications of the AI Act for medical devices cannot be viewed in isolation from the existing regulatory framework. Rather, it requires an integrated approach that takes into account both traditional safety and clinical performance requirements as well as the new obligations specific to AI systems.

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Feedback From Swissmedic



From health software to artificial intelligence in medical devices: Navigating the regulatory landscape

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Health software can encompass a broad range of functions and may qualify as a medical device under Swiss and European Union (**EU**) law if it is intended to be used for a medical purpose, thus making it subject to medical device regulations. Medical device software incorporating artificial intelligence (**AI**) introduces additional considerations, including data dependency, limited interpretability, and the potential for adaptive systems to change behaviour after deployment. Even though Switzerland has not yet adopted dedicated AI legislation, the existing medical device regulatory framework, along with international standards and best practice guidance, provides the necessary foundation for ensuring adequate safety and performance of AI-based medical devices. As the regulatory landscape continues to evolve rapidly, developments should be continually monitored by manufacturers and regulators alike.

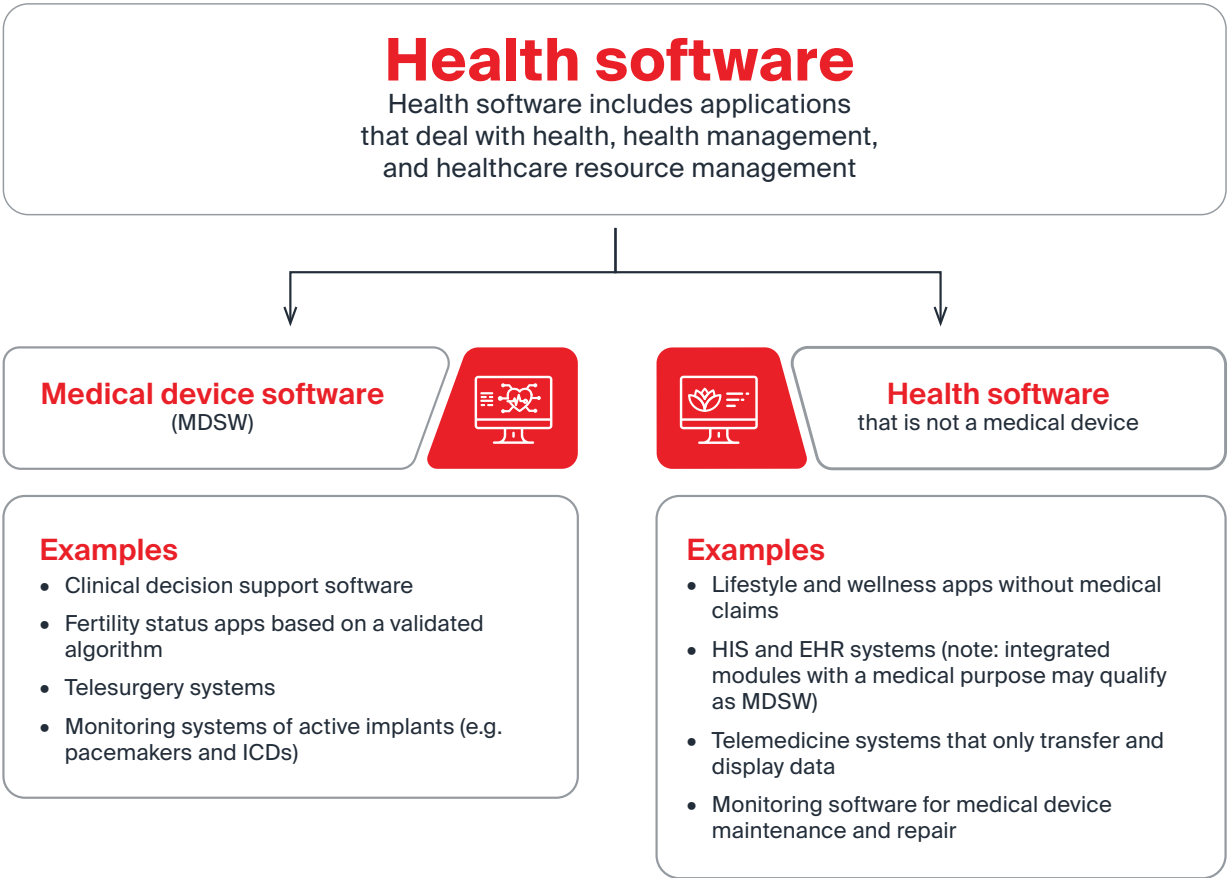
Health software: Scope and categories

Modern health software performs a wide range of functions, such as data management, patient monitoring, and clinical decision support. It can be deployed across a variety of platforms, from software embedded in a specific medical device (e.g. a pacemaker) to desktop applications, mobile applications, and cloud-based systems.

The International Electrotechnical Commission (IEC) defines health software in its IEC 82304-

1:2016 standard as software intended to be used specifically for managing, maintaining, or improving the health of individual persons or the delivery of care. As illustrated in **Figure 1**, health software includes applications dealing with health, health management, and healthcare resource management. Within health software, two categories can be distinguished depending on whether medical device regulations apply: medical device software (**MDSW**) and health software that is not a medical device.

Figure 1: Regulatory distinctions of health software



EHR: electronic health record
HIS: health information system
ICD: intra-cardiac defibrillator
MDSW: medical device software

Medical device software is subject to medical device regulations. The following are examples of MDSW:

- clinical decision support software (e.g. for drug planning in chemotherapy or for the automatic analysis of X-ray images)
- applications intended to support conception by calculating fertility status based on a validated algorithm
- telesurgery systems
- web systems used to monitor active implants such as pacemakers or intra-cardiac defibrillators (**ICDs**).

In contrast, health software that is not considered a medical device is not subject to medical device regulations. The following are examples of such health software:

- lifestyle software without medical claims (e.g. fitness, nutrition, or sleep applications)
- hospital information systems (**HIS**) and electronic health record (**EHR**) systems (modules integrated into or operating alongside such systems may, however, qualify as MDSW if they fulfil a medical purpose)
- telemedicine systems that only transfer or display information for monitoring purposes without interpreting data
- software used in hospital systems for the monitoring, maintenance, or repair of medical devices.

Which health software is subject to medical device regulations?

In Switzerland, software qualifies as a medical device^A if it meets the criteria set out in Article 3, paragraphs 1 and 2 of the Medical Devices Ordinance (**MedDO**) or Article 3, paragraphs 1 and 2 of the Ordinance on In Vitro Medical Devices (**IvDO**). These criteria are

materially aligned with the corresponding definitions in the European Union's Medical Device Regulation (**MDR**) and its In Vitro Diagnostic Medical Devices Regulation (**IVDR**). In essence, the manufacturer must intend for the software to be used (alone or in combination with other products) for a medical purpose such as the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of a disease. More specifically, and according to the EU's Medical Device Coordination Group's (**MDCG's**) guidance document MDCG 2019-11 Rev. 1 on the qualification and classification of software under the MDR and IVDR, software will generally qualify as MDSW if all of the following three criteria apply:

- It has a medical purpose as defined in the applicable regulation.
- It performs an action on data beyond mere storage, archiving, communication, simple search, or lossless compression.
- It is intended for the benefit of individual patients.

Whether software has a medical purpose depends on its intended purpose as defined by the manufacturer. Intended purpose means the use for which a product is intended according to the information supplied by the manufacturer on the product's label, instructions for use, promotional or sales materials, or as specified in the clinical or performance evaluation (MDR, Art. 2(12); IVDR, Art. 2(12)).

Qualification as a medical device is independent of its location (e.g. desktop, mobile app, or embedded in hardware) and its intended user (e.g. healthcare professional or layperson). Even if software itself does not qualify as a medical device, it may still be covered by medical device legislation if it qualifies as an accessory to a medical device or falls within the scope of an MDR Annex XVI product.

^AFor the purposes of this text, references to a "medical device" include both medical devices under the Medical Devices Ordinance (MedDO) and in vitro diagnostic medical devices under the Ordinance on In Vitro Diagnostic Medical Devices (IvDO).

Crafting a clear and precise intended purpose is therefore critical for correct qualification and regulatory compliance. MDCG 2019-11 Rev. 1 and the European Commission's infographic *Is Your Software a Medical Device?* (see **Figure 2**) both provide useful guidance regarding the qualification and classification of software. Additional information can be found in the MDCG's guidance on MDSW meant to be used with hardware or hardware components (MDCG 2023-4) and the MDCG's *Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices*.

Medical device software incorporating artificial intelligence

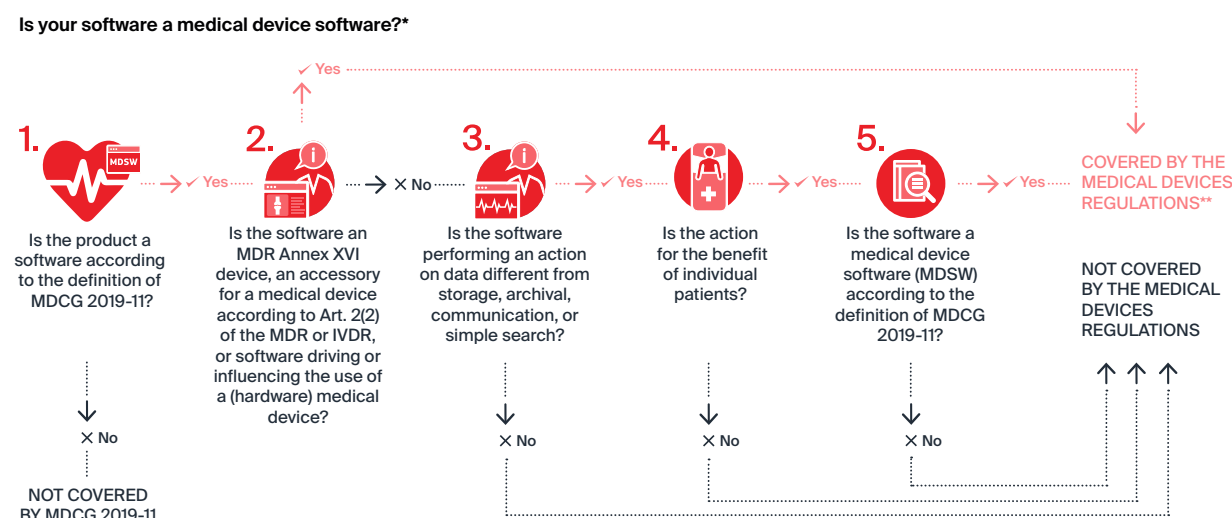
Medical device software can incorporate artificial intelligence (AI). AI refers to the use of computational models to perform tasks that typically require human intelligence. The EU's *Artificial Intelligence Act (AI Act)* defines an AI system as "a machine-based system that is designed to operate with varying levels of autonomy

and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments" (Article 3(1)). The predominant form of AI in MDSW is machine learning models, which are most commonly used for image analysis, clinical decision support, or risk prediction.

The use of AI introduces unique considerations, including the following:

- the data-driven nature of model development
- the limited interpretability of many models
- the dependence of performance on the quality and representativeness of training data
- challenges of reliably evaluating system behaviour
- the potential of adaptive systems to change behaviour after deployment.

Figure 2: Decision steps to assist the qualification of medical device software



* Medical device software (MDSW): Software that is intended to be used alone or in combination for a purpose as specified in the definition of a medical device in the Medical Device Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR)

** Medical devices regulations refer to two applicable regulations: The EU's Medical Device Regulation (MDR) and the EU's In Vitro Diagnostic Medical Devices Regulation (IVDR)

Currently, Switzerland does not have a dedicated AI regulation. Rather than adopting a comprehensive, cross-sectoral AI framework comparable to the AI Act, legislative developments are expected to follow a sector-specific approach.

In the absence of a direct regulation, the unique characteristics and risks of MDSW incorporating AI must be addressed within the existing regulatory framework, which includes the following regulations and international standards, among others:

- MedDO/MDR
- IvDO/IVDR
- MDCG endorsed documents and guidance relevant to MDSW
- International Organization for Standardization (**ISO**) standards for quality management systems (ISO 13485), for risk management (ISO 14971), for clinical investigations of medical devices for human subjects (ISO 14155), and for clinical performance studies using specimens from humans involving in vitro diagnostic medical devices (ISO 20916)
- International Electrotechnical Commission (**IEC**) standards for medical device software life cycle processes (IEC 62304), for the application of usability engineering to medical devices (IEC 62366 Part 1 and Part 2), and for health software (IEC 82304 Part 1).

Global AI standards are only applicable to a limited extent in the medical device context, and dedicated standards for AI in medical devices are still under development. Therefore, useful orientation can be found in the following best practice principles and other guidance documents, among others:

- International Medical Device Regulators Forum (**IMDRF**) Good Machine Learning Practice for Medical Device Development: Guiding Principles
- German Notified Bodies Alliance for Medical Devices (**IG-NB**) and The European Association of Medical devices Notified Bodies' (**Team-NB**) joint position paper Questionnaire: Artificial Intelligence in Medical Devices (Version 1.1)

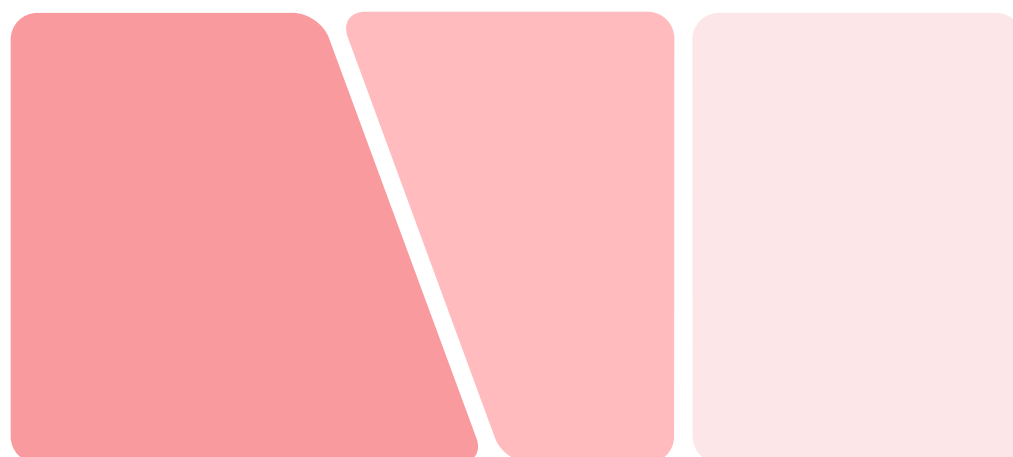
- British Standards Institution (**BSI**) and Association for the Advancement of Medical Instrumentation (**AAMI**) Application of ISO 14971 to Machine Learning in Artificial Intelligence: Guide (BS/AAMI 34971:2023).

Swiss manufacturers operating in the EU market must comply with the AI Act's requirements. Under the AI Act, AI systems intended for use as medical devices are currently classified as high risk and are subject to various obligations. Swiss manufacturers are therefore well advised to align their development and quality management practices with these requirements from the outset. At the same time, the regulatory landscape for AI in the healthcare sector is evolving rapidly. Recent legislative amendments and proposals at the EU level – notably the Digital Omnibus on AI (in force since 27 July 2026) and the proposed MDR/IVDR amendments (December 2025) – indicate that the regulatory framework is subject to ongoing change. These developments should be continually monitored by manufacturers and regulators.

Ultimately, manufacturers must demonstrate that software incorporating AI achieves an adequate level of safety and performance and meets its defined intended purpose. While Switzerland currently lacks AI-specific legislation, the existing medical device regulatory framework provides the necessary foundation. This framework must be applied in a way that appropriately addresses the specific risks and characteristics of AI-based medical devices, thus ensuring robust assurance of safety and performance throughout the product life cycle.

Note: Swissmedic is the competent authority responsible for the surveillance and enforcement of medical device regulation in Switzerland; it is not responsible for the development of the legislative framework.

Feedback From swissethics



Ethical challenges related to artificial intelligence in clinical research

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While existing ethical principles and regulations are fully applicable to clinical research on or using artificial intelligence (**AI**), research in this field introduces new aspects that challenge the current standard approaches to the oversight, accountability, and governance responsibilities of researchers, sponsors, and ethics committees. In recent years, several frameworks and guidance documents have appeared that offer practical, decision-oriented tools to support researchers, sponsors, and ethics committees in their roles. Yet given the dynamic nature of developments in AI, it can be difficult to maintain a clear overview of AI's ethical implications in clinical research. This article highlights the most important ethical challenges related to AI and clinical research.

Preliminary question: Research focus or tool?

To begin with, we must first differentiate between:

1 artificial intelligence (**AI**) as the subject of an investigation *in research* (i.e. an AI system is the focus of research and is the intervention under investigation, an AI system is investigated systematically and intended to contribute to generalisable knowledge, etc.) and **2** AI used as a tool *to administer research* (i.e. AI supports the operative aspects of research and is used, for example, to draft the research protocol, optimise patient recruitment, enhance safety monitoring, etc.).

Answering this preliminary question is critical in order to determine whether a given clinical research activity involving AI classifies as research under Switzerland's Human Research Act (HRA).

When AI is the focus of a trial and an intervention under investigation, ethics committees evaluate, among other aspects, the AI's provenance (i.e. the documented history, origin, and lifecycle of the AI system, including the data, algorithms, and hardware used to create and operate it) as well as its intended use, validation status, and risk profile. These topics will be addressed in more detail in the following sections. When AI is limited to operational support, approval by an ethics committee for that specific use is not required under Swiss law, but the ethical challenges remain. Researchers and sponsor(s) of a clinical trial are ultimately responsible for proper governance, fairness/equitability, and transparency as well as human oversight.

In practice, AI is frequently used in activities that straddle the boundary between research, quality improvement, and operational analytics – which raises different ethical questions and concerns than in clinical research without AI. Many frameworks, guidelines, templates, and other resources have been created to help researchers, sponsors, and ethics committees approach AI in clinical research (see **Resources and further reading** at the end of this article).

Ethical questions and concerns

When AI systems are the focus of clinical research, ethical issues, use practices, and regulatory status evolve as the AI systems move from conceptual development to real-world clinical use.

In the *discovery stage*, AI systems are typically trained and developed using existing datasets. During this early stage, ethical questions and concerns are related to data provenance, whether data was originally collected with appropriate consent, whether secondary data uses are ethically and legally justified, and study participants' identifiability. Given modern re-identification techniques, participants' data, even if nominally anonymised, may remain linkable to their IDs. Today, there is general agreement that we need to move beyond binary notions of "identified" versus "anonymous" data and instead assess the realistic risk of linkage.

In the *translation stage*, researchers focus on validation, performance assessment, and risk characterisation. An AI system's intended use must be clearly specified and aligned with the objectives of the research. Researchers must also consider whether future applications might fall under the scope of the Medical Devices Ordinance (MedDO) or the Ordinance on In Vitro Diagnostic Medical Devices (IvDO). Performance metrics – such as accuracy and precision, sensitivity and specificity, usability, etc. – are not merely technical or operational matters but ethical indicators of potential harm, bias amplification, injustice, and inequitable impact.

The *deployment stage* represents the highest risk context. During this stage, AI systems directly influence clinical decision-making, diagnosis, treatment, and/or study participants' outcomes. Researchers and sponsors must ensure high-level human oversight, real-time monitoring, clarification of the regulatory status of AI (e.g. software as a medical device), and procedures for responding to performance drift. AI systems used as companion diagnostics or clinical decision support tools are both high value and high risk, and they require ongoing accountability and oversight rather than merely one-time (initial) ethical approval.

These three stages can certainly coexist in one research project.

Algorithm stability and adaptive learning

Traditional clinical trials are event-based and built around research protocols with static interventions. AI systems, by contrast, may continuously learn, update, or adapt in response to new data, and researchers and sponsors must define if they are “locked” or if they are adaptive algorithms. Adaptive algorithms introduce the possibility that risk profiles may change during the course of the research. In this case, researchers and sponsors must predefine limits to the changes allowed as well as define monitoring protocols and triggers for audits, rules for rollbacks, and triggers for amendment submissions. Researchers and sponsors must embed these elements into their research protocols.

Data identifiability, governance, and secondary use

With AI research, attention must be given to the increasing feasibility of re-identification, especially when large datasets are combined or processed using generative AI (**GenAI**) and large language models (**LLMs**). Ethics committees must assess not only whether data protection legislation and standards are being complied with but also how likely it is that someone could re-identify study participants. Safeguards – such as data coding, secure IT environments (e.g. through the use of the Swiss Personalized Health Network’s (**SPHN’s**) [Excel Use Case Evaluation and Risk Assessment Template](#)), and contractual restraints (e.g. data transfer and use agreements (**DTUAs**)) – are essential elements of ethical AI research.

Attention must also be given to the ethical issue of data retention when participants withdraw from studies. Once data are incorporated into trained AI systems, removal of those data may no longer be technically feasible. This must be transparently disclosed to study participants during the informed consent process.

Additional ethical considerations

There are specific domains that require caution in clinical research when AI is the subject of an investigation: technical robustness and safety, confidentiality and data governance, transparency, representativeness and fairness, and informed consent. In all these domains, it is crucial to emphasise the importance of preserving human judgment. AI outputs should inform, not replace, clinical decision-making, and research protocols should specify how researchers and treating clinicians can override or question AI recommendations. Having training requirements, the ability to understand and explain decisions, and accountability are ethical safeguards rather than optional best practices.

Fairness and representativeness must receive sustained attention. It is evident that AI systems trained on unrepresentative datasets can exacerbate disparities. Thus, researchers and ethics committees must question dataset provenance and composition, assess differential impacts on underrepresented populations, and consider access barriers such as digital literacy and technology availability.

Finally, informed consent is an evolving process rather than a static document. Study participants must be meaningfully informed about how AI systems operate within the research they are involved in, how their data may be reused, and what risks arise from data linkage and algorithmic inference. Researchers and ethics committees must approach the informed consent process from the perspective of what a reasonable person would want to know about research on AI.

Conclusion

As AI becomes increasingly integral to the clinical research life cycle, from discovery to translation and deployment, the *informed* development and use of AI seem to be the most present ethical challenges for researchers, sponsors, institutions, funders, study participants, ethics committees, and regulatory authorities. It is an ethical imperative to ensure that those involved in research are properly trained so that they can develop AI systems and use AI tools in a responsible manner. This is to protect study participants, maintain public trust and ensure that innovation proceeds responsibly. All those involved in research are called upon to fulfil their responsibilities in full compliance with fundamental ethical principles and with the established principles of scientific integrity.

Acknowledgment: I would like to thank Dr Isabelle Wienand for her critical review of the manuscript and valuable comments.

Resources and further reading

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Views and Opinions

SCTO perspective



Building the future of AI in Swiss clinical research

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The Swiss Clinical Trial Organisation (**SCTO**) has established a new project group called the National Priority Project on AI in Clinical Research in order to explore developments at the intersection of artificial intelligence (**AI**) and clinical research as well as the opportunities and challenges they bring. In this article, project lead Anastasios Stathis introduces the project group and its objectives and shares his perspectives on emerging applications of AI as well as current barriers to their implementation. In addition, he reflects on how the project group could contribute to Switzerland's clinical research landscape in the coming years.

As a clinician and researcher working in Switzerland, how do you see artificial intelligence (AI) evolving in both clinical practice and clinical research?

AI will increasingly support clinical decision-making, data interpretation, and operational efficiency across healthcare systems. In clinical research, it has the potential to accelerate trial design, feasibility assessments, patient identification, and data analysis. In addition to bringing efficiency gains, AI may also help generate new insights from complex biomedical datasets. However, successful implementation will require robust validation, transparency, and governance frameworks to ensure that AI remains a tool that enhances, rather than replaces, scientific and clinical judgment.

Where do you see the first concrete use cases emerging for implementing AI in clinical trials?

The first practical applications will likely emerge in patient recruitment, protocol feasibility assessments, automated data extraction from electronic health records, and risk-based trial monitoring. These are areas characterised by significant operational burdens and large volumes of structured and unstructured data, making them particularly suitable for AI-supported solutions.

Where do you see the main barriers today for the SCTO's clinical research centres (CRCs) and researchers when it comes to using AI in clinical research?

The main barriers include poor data quality, a lack of interoperability, limited digital infrastructure, regulatory uncertainty, and a shortage of AI expertise within CRCs and research teams. Equally important are issues related to governance, explainability (i.e. the extent to which an AI system's outputs and decisions can be explained in understandable terms), the validation of AI tools, and trust among researchers, patients, and regulators.

In your experience, which parts of the clinical trial process could benefit most from AI support (e.g. design, feasibility, recruitment)?

Recruitment and feasibility are probably the areas where AI could have the highest immediate impact, as they remain major bottlenecks in trial execution. AI can also support protocol optimisation by identifying

overly restrictive eligibility criteria, improving study efficiency, and reducing unnecessary complexity. Over time, AI is likely to contribute across the entire trial life cycle.

In a field like oncology, where data are abundant and complex, do you see specific added value for AI-based approaches compared to traditional approaches?

Absolutely. Oncology generates large, multi-dimensional datasets, including clinical, imaging, molecular, genomic, and longitudinal outcome data. AI methods can integrate these diverse sources and identify patterns that are difficult to detect with traditional analytical approaches, which then facilitates biomarker discovery, patient stratification, and more personalised treatment strategies.

You are leading a new project group for the SCTO on AI in clinical research. Could you briefly share its overall aim?

The National Priority Project on AI in Clinical Research aims to create a collaborative national platform to explore how AI can be implemented responsibly, effectively, and ethically in clinical research in Switzerland. Our objective is not only to identify promising AI applications but also to map existing tools, assess unmet needs, engage stakeholders, and develop practical recommendations that support the adoption of AI across the Swiss clinical research ecosystem.

How do you see this project group contributing to Switzerland's clinical research landscape both in the near future and over the next few years?

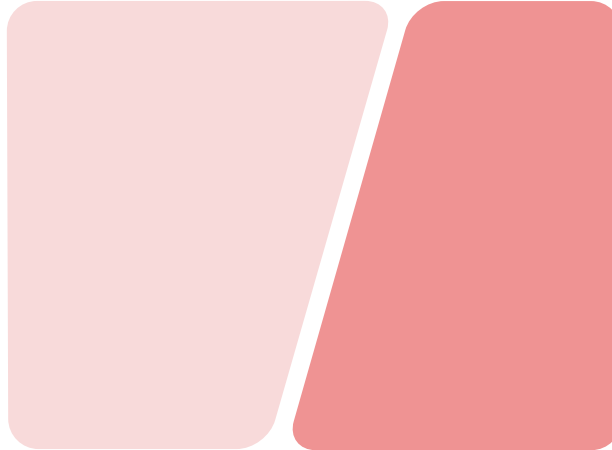
In the short term, the group aims to raise awareness, share best practices, and identify high-impact use cases. In the longer term, we hope to contribute to harmonisation efforts, support the development of infrastructure and governance frameworks, facilitate pilot projects, and help position Switzerland as a leader in the responsible and trustworthy use of AI in clinical research.

What infrastructure needs to be in place at individual institutions/CRCs in order to use AI more safely and effectively in clinical research?

Institutions need secure and scalable data infrastructures, interoperable systems, robust governance frameworks, and access to computational and data science expertise. Standardised validation and auditing procedures, together with AI literacy training for researchers and study teams, will be equally important. Ultimately, successful implementation requires not only technology but also a culture that promotes responsible innovation.

Views and Opinions

Legal perspective



AI in clinical research: Regulatory and legal uncertainties in protecting participants' rights

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In the context of clinical research, machine learning algorithms can improve participant recruitment, enhance patient safety, accelerate clinical trials, and reduce associated costs. However, the growing integration of artificial intelligence (**AI**) also raises a number of legal and ethical concerns, including issues related to transparency, data quality, algorithmic bias, and the protection of participants' consent. Moreover, the development and deployment of AI systems raise complex questions regarding the allocation of responsibility among the various actors involved in the AI development chain. The current legal framework remains fragmented and does not provide a comprehensive response to all these challenges. This fragmentation may, to some extent, undermine the coherence of AI regulation in clinical research. Normative uncertainties also arise where the protection of patients' and participants' rights, including data protection and non-discrimination, requires reconciling competing legally protected interests. These issues are illustrated by the regulation of health data and by the challenges posed by algorithmic bias in clinical research.

Legal and regulatory landscape surrounding AI in clinical research

The legal and regulatory framework governing artificial intelligence (AI) in clinical research is fragmented in both Europe and Switzerland. While the European Union (EU) has taken an important regulatory step by adopting the [Artificial Intelligence Act \(AI Act\)](#), the specific challenges posed by medical AI are not addressed in a dedicated framework. The AI Act must therefore be interpreted alongside other risk-based instruments such as the EU's [Medical Device Regulation \(MDR\)](#) and the [European Health Data Space \(EHDS\) Regulation](#) as well as rights-based instruments such as the EU's [Charter of Fundamental Rights](#).

Although Switzerland has legislation that adapts the MDR framework to its domestic legal order, it has not mirrored the EU approach for AI and does not currently plan to adopt a comprehensive regulatory framework for artificial intelligence. However, Switzerland recently signed the first international treaty on AI and human rights, which will also apply to health care: the [Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law](#). This treaty requires contracting states to implement concrete measures to safeguard fundamental rights such as autonomy, non-discrimination, and digital literacy. While this international instrument establishes general principles, it may eventually be complemented by more specific domestic regulations, which remains an option for medical AI in Switzerland.

Beyond AI-specific regulatory frameworks, the field remains subject to a range of pre-existing general legal norms. Yet while the regulatory debate primarily focuses on how to regulate AI prospectively, certain gaps and shortcomings have already arisen from these existing legal frameworks, with potential implications for the rights and interests of patients and research participants. One important issue concerns the capacity of current frameworks to effectively prevent algorithmic bias that may lead to discriminatory outcomes.

Risks of bias and discrimination

The risks of biases in AI systems are now well documented and have multiple sources.^{1,2} In the context

of clinical research, biased datasets may emerge from long-standing research practices, such as the quasi-systematic exclusion of certain categories of participants. For instance, people over 65 years old are regularly excluded from clinical trials, so they are often under-represented in Alzheimer's trials.³ In addition, women have historically been under-represented in many clinical studies due to study exclusion based on gender-specific factors such as pregnancy, childbearing age, and menopause.⁴ Such disparities in participation can lead to biased training data and consequently to qualitative disparities in algorithmic predictions. When these inequities amount to unjustified differences in treatment based on legally protected characteristics, they violate the principle of non-discrimination (regardless of whether discriminatory intent existed) and potentially constitute direct discrimination.

However, risks of algorithmic biases are not limited to situations in which legally protected groups are explicitly excluded. They may also arise from the definition of objectives, such as longevity matching in healthcare resource allocation algorithms, which may disproportionately affect older patients, chronically ill individuals, or persons living with disabilities.⁵ These risks often stem from political and design choices made upstream of the deployment of machine learning systems.

Whether biases result from a data quality problem (the well-known "garbage in garbage out" issue) or from design choices, they may be partly mitigated by increasing fairness awareness and developing fairness metrics. The EU's AI Act, for example, requires that particular attention is paid to data governance, including data selection and preprocessing. However, other legal standards designed to protect individuals may sometimes affect how inclusive and representative health datasets can be obtained to train fair AI systems. In such situations, legal trade-offs may be made, potentially leading to new forms of bias.

Data protection, consent models, and selection bias

Respecting and protecting the various rights of patients and research participants may generate tensions between competing rights, ultimately

requiring balance and compromise. The legal framework governing the collection and use of health data, which constitute personal data protected by law, provides a good illustration of these tensions. In Switzerland, the development of AI systems within the context of clinical research falls within the scope of the Human Research Act (HRA), which applies to health-related personal data unless they have been effectively anonymised (HRA, Art. 2).

As a general rule, individuals participating in a research project must be informed about the nature, purpose, and duration of the project as well as its foreseeable risks and expected benefits, and their informed consent must be obtained (HRA, Art. 16). When research is conducted on data that were originally collected for a different purpose (i.e. in the case of secondary or further use of data), consent must be obtained at the time of the original health data collection and individuals must be informed of their right to object (HRA, Art. 17). In addition, Article 33 of the HRA provides two possible legal bases for the reuse of non-genetic health data: *explicit consent* (informed consent), in which case the data may remain uncoded, and *implicit consent* (when the person concerned has been duly informed and has not objected), in which case the data must be coded. The further use of genetic data, by contrast, requires informed consent regardless of whether the data are coded or not (HRA, Art. 32). The concrete modalities of consent and the scope of information to be given to participants are further specified in the Human Research Ordinance (HRO), Chapter 3).

While these provisions are essential for protecting individuals' self-determination, they may also introduce selection biases depending on the consent model used. Empirical evidence suggests that participation patterns differ across consent models. In particular, opt-in mechanisms may lead to the over-representation of certain population groups depending on their linguistic, age-related, or socio-economic characteristics.⁶ More broadly, systematic reviews have shown that different consent procedures can significantly affect participation rates and introduce consent-related selection bias in research datasets.⁷ Such disparities in model training, which result from strong protections of participant autonomy, may therefore reduce the volume and diversity of data available for training machine learning

systems, especially for groups that are already under-represented. This can potentially lead to inequitable outputs.

Challenges of algorithmic decision-making

These legal trade-offs reflect the necessary compromises that legal and regulatory frameworks must strike. Yet beyond considering these trade-offs, legal scholarship has only modestly begun to address the deeper conceptual challenges posed by algorithmic decision-making. This is particularly evident in situations where algorithms identify correlations and construct algorithmic groups to which harmful decisions may subsequently be applied. This may occur when AI systems classify individuals as dog owners, sad teens, or single parents in order to allocate resources.⁸ Individuals may then suffer harm not because they belong to historically protected groups but because they are classified within newly constructed algorithmic categories. Such forms of algorithmic harm may escape traditional anti-discrimination frameworks because legislation is primarily designed to protect groups that have been historically stigmatised in the social world.⁶ While legal protections must remain attentive to social realities, the increasing digitisation of health care and the opacity of many algorithmic systems suggest that legal and regulatory frameworks should also adapt to these emerging algorithmic realities and develop tools capable of addressing new forms of algorithmic harm.

Conclusion

The challenges presented by AI in clinical research do not stem solely from the absence of AI-specific regulation. They also reveal tensions and limitations within existing legal frameworks, particularly where the protection of autonomy, data governance, and non-discrimination intersect. As AI systems become increasingly embedded in health research, paying greater attention to these tensions and to the interpretation of rights in the digital context may help ensure that innovation and the protection of research participants' rights evolve in a mutually reinforcing manner.

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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

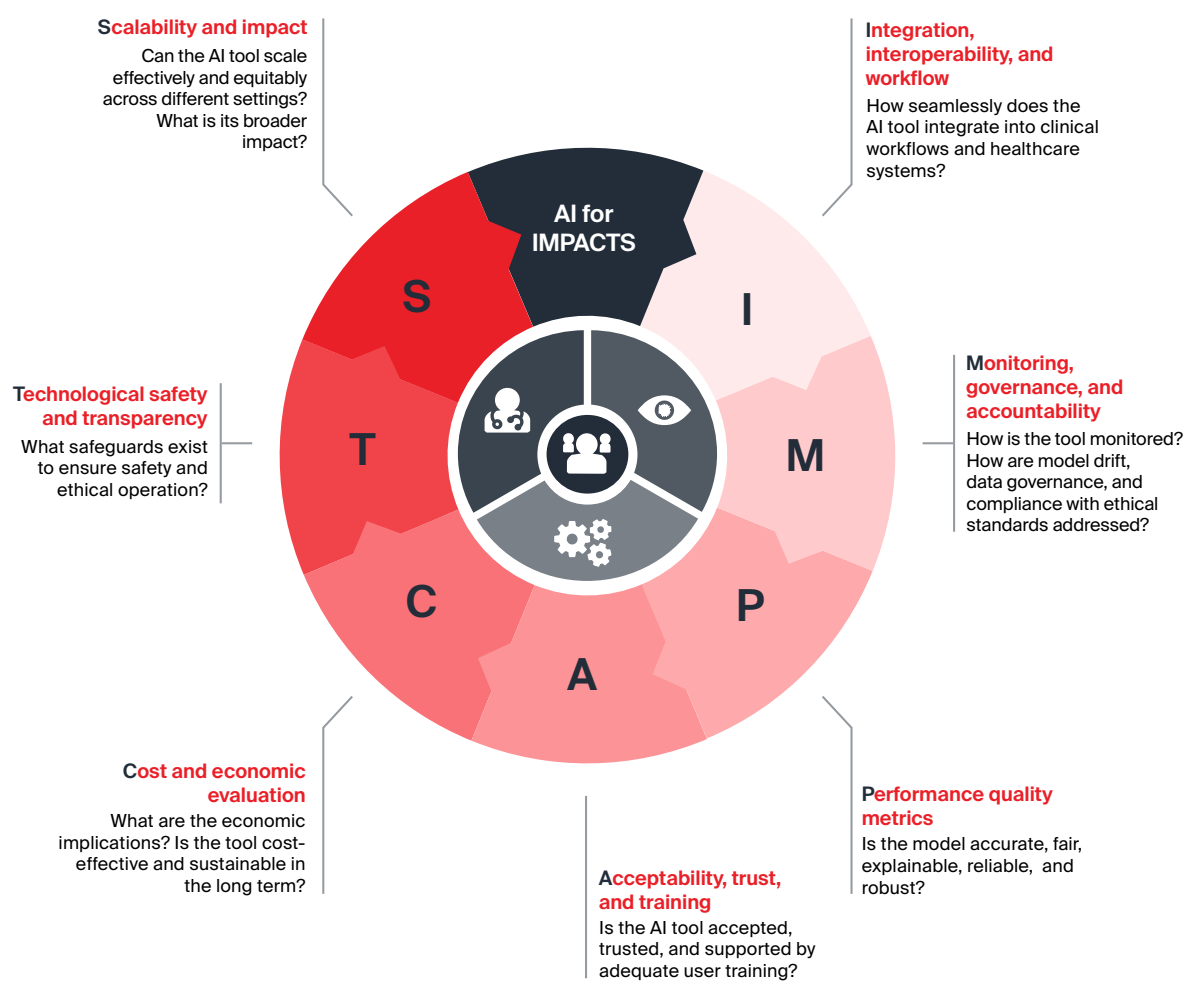
AI assessment guidelines, however, remain narrowly focused on accuracy or methodological rigour and neglect social and organisational dimensions.¹³ In response to this gap, the AI for IMPACTS framework was developed through a collaborative effort involving several Swiss universities as well as clinical 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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Views and Opinions

Clinical trial management



Incorporating artificial intelligence into clinical trial management

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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.

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Views and Opinions

Large language models



Large language models in clinical research: Risks and opportunities

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Large language models (**LLMs**) are rapidly entering clinical research, with applications ranging from evidence synthesis to protocol development and data extraction. Their ability to process large volumes of text offers efficiency gains. However, recent evidence shows that most evaluations of LLMs are based on simulated or low-complexity tasks, with limited validation in real clinical settings. Only a small fraction of LLM studies use real patient data, and randomised trials on LLMs remain rare. This creates a gap between the perceived capability of LLMs and their actual clinical value. This gap is key for clinical research, where transparency, traceability, and reliability are essential. LLMs should therefore be viewed as assistive tools having clear potential but requiring careful validation and governance before being more broadly integrated into regulated workflows.

The role of LLMs in clinical research

A large language model (**LLM**) is a type of artificial intelligence (**AI**) trained on large amounts of language data to process and generate human language. An LLM can answer questions, summarise documents, and produce written content based on patterns learned from data. LLMs have entered clinical research at a high speed. Since 2022, thousands of studies have explored their use in medicine, covering tasks from literature review to clinical decision support. This growth reflects the strong interest in and clear potential of LLMs.

But what does the evidence from studies involving LLMs actually show? A closer look reveals a mismatch. While the number of studies involving LLMs is large, most of them do not reflect real clinical practice. Many are based on exam-style questions, simulated cases, or curated datasets. Studies using real patient data are far fewer, and prospective trials, including randomised controlled trials (**RCTs**), are rare. The result is a rapidly expanding field with an uncertain evidence base.¹

Clinical research areas where LLMs can make the most impact

Despite these limitations, several areas stand out where LLMs could support clinical research. The first area is evidence synthesis, including systematic review. Screening, extracting, and summarising scientific literature are time-consuming tasks. LLMs can assist in structuring large bodies of evidence and may enable more frequent updates of systematic reviews. For example, LLMs can help in screening large bodies of abstracts for eligibility in systematic reviews or extracting specific data from papers.

The second area comprises clinical trial protocol development and trial design. LLMs can help draft eligibility criteria, summarise prior trials, and identify common endpoints. This may reduce the administrative burden and support more consistent documentation.

The third area that can benefit considerably from LLMs is unstructured text from clinical documentation. Much clinical data (e.g. electronic health records (**EHRs**)) exist in free-text form. LLMs can help convert this information into structured formats that are easier to analyse.

In addition to these core applications, LLMs may support other clinical research tasks. They can assist with drafting or reviewing protocols, informed consent forms, and other regulatory documents – for example by extracting protocol information, checking consistency across documents, or generating first drafts. However, such uses require human review because LLMs may alter required wording, omit information, or introduce factual errors. Studies evaluating LLM-generated clinical trial documents have shown both potential efficiency gains and substantial limitations in regulatory compliance and factual accuracy.

LLMs may also support participant communication. For example, they have been used to convert trial protocols into patient-facing informed consent materials and to answer trial-specific questions using information retrieved from study documents. Other applications include extracting structured information such as eligibility criteria, interventions, and endpoints from trial protocols or other unstructured clinical text; identifying missing or inconsistent information; and structuring protocol content for downstream trial workflows. These applications remain largely experimental and should generally be used as decision or drafting support rather than as substitutes for expert review.

Some applications go further but remain largely exploratory for now. For example, LLMs are discussed in the context of digital twins or trial simulation, where they may help structure patient data or connect it to existing evidence. However, they do not model disease mechanisms and cannot replace predictive or causal models. Other ideas include automated protocol optimisation or real-time decision support during trials. All these use cases are promising, but they raise an important question: how well do these tools perform in real-world conditions?

LLMs' central limitation: Evidence does not reflect clinical reality

The main issue is not what LLMs can do but how they are evaluated. Most studies test LLMs in simplified settings. For example, models are asked to answer multiple-choice questions or interpret short case descriptions. These tasks are easy to standardise and measure, but they are disconnected from real clinical workflows. This evaluation is often called validation: testing whether a model performs reliably for its intended use, ideally on new data and in realistic settings. Because validation sits between model development and deployment, strong performance on a simplified benchmark does not necessarily mean that the model will work reliably in practice.

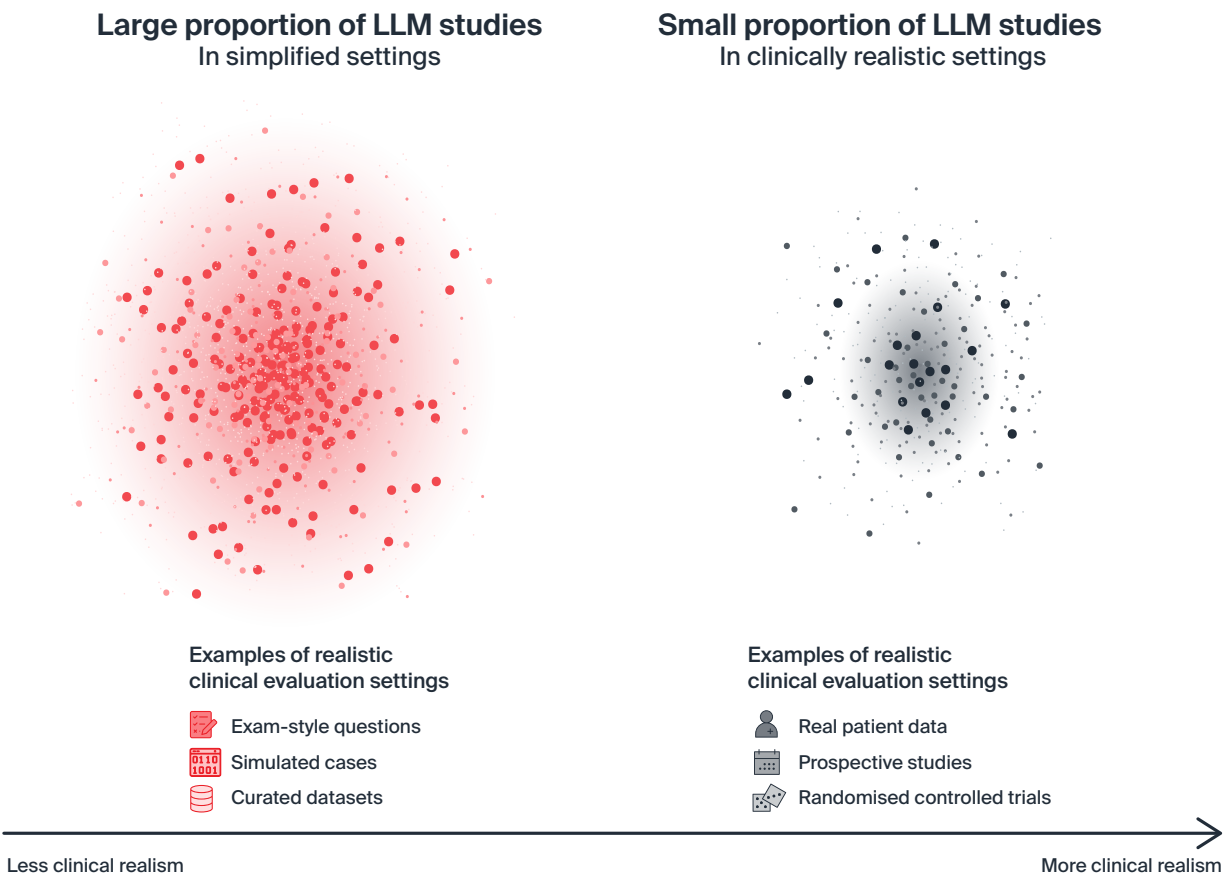
Only a minority of studies use real patient data for the performance evaluation of LLMs.¹ Even fewer studies test LLMs prospectively in clinical environments. LLMs are still rarely evaluated in RCTs, which are often considered the gold standard for evaluating interventions. This matters because performance depends strongly on context. Models often perform well on structured, knowledge-based tasks. But real clinical research involves incomplete data, ambiguity, and complex decision-making. LLMs' performance on simplified tasks may not reflect how they perform when applied to more complex tasks, such as those in real clinical settings. In addition, many studies have a small sample size and/or dataset and lack external validation.¹ This limits confidence in their reported results. Taken together, the current evidence base for LLM performance in clinical research – despite seeming promising at first glance – is not sufficient to support the widespread use of LLMs in clinical settings.

What do performance comparisons really show?

Some studies directly compare the performance of LLMs and clinicians on specific tasks, such as answering medical questions, interpreting clinical cases, making diagnostic decisions, or recommending management. For example, a randomised trial was conducted involving 50 physicians and challenging diagnostic vignettes. GPT-4 alone outperformed the physicians; however, access to GPT-4 did not improve physicians' diagnostic reasoning compared with conventional resources.² At first glance, study results may seem encouraging: in some cases, models perform similarly to or better than humans. But these comparisons need careful interpretation. Performance varies depending on a variety of factors, including the type of task, the extent to which the data reflect real-world clinical practice, and the experience level of the human comparator. LLMs tend to perform best on structured knowledge tasks and less well in realistic clinical scenarios. Moreover, they perform worse when compared to experienced clinicians rather than trainees.

So the key question is not "Can LLMs pass exams?" but rather "Can they support real clinical decisions reliably?" At present, the evidence for such support is limited. **Figure 1** provides a conceptual illustration of this evidence gap based on patterns observed in the literature rather than a systemic synthesis: while many studies assess LLMs in simplified or structured settings, much less evidence comes from real patient data, prospective studies, or randomised controlled trials.

Figure 1: Schematic illustration of large language model (LLM) performance in clinical research



Challenges of using LLMs in a regulated research environment

Clinical research operates under strict regulatory and quality requirements. Data must be accurate, traceable, and reproducible. Decisions must be transparent and auditable. LLMs challenge these principles in several ways. For example, they can generate plausible but incorrect information, and these errors are not always easy to detect. And often, it is not possible to trace outputs to source data, which makes verification difficult. In addition, many widely used models are closed systems, which means that users cannot fully see how a model was trained, what data it was trained on, or how it changes over time. This limits reproducibility, because researchers may not be able to explain why a model produced a specific output or whether the model would produce the same output after an update(s).

There are also concerns about bias, data privacy, and the use of sensitive information. These are not abstract risks in a regulated research environment: they may directly affect data integrity, regulatory compliance, and trust in research outputs.

A pragmatic path forward

So how should clinical research respond to these challenges? LLMs should not be treated as autonomous systems. They are better understood as assistive tools that support specific tasks under human oversight. For example, an LLM may draft eligibility criteria for a clinical trial or extract variables from published studies, but researchers should verify the output against the original protocol or publication before it is used. In addition, a structured approach is

needed: start with well-defined, low-risk use cases; then validate LLM performance on real clinical data and move to prospective studies; and only then consider broader implementation. Furthermore, documentation is essential. Inputs, outputs, and verification steps should be recorded to create an audit trail. Moreover, an LLM should be tested on the actual task and setting in which it will be used. Good performance on general benchmark questions does not necessarily mean it will perform well in a specific clinical research workflow. Most importantly, LLMs should be evaluated in settings that more closely reflect real clinical practice.

Conclusion

LLMs have clear potential to improve efficiency in clinical research. They can support evidence synthesis, documentation, and data structuring. But current evidence on the performance of LLMs is largely based on simplified tasks and in many cases does not reflect real-world use. The key challenge is not technological capability but validation. For now, LLMs should be used cautiously, with clear human oversight and defined roles. Their future in clinical research will depend less on what they can generate – and more on how reliably they can be integrated into rigorous, transparent workflows.

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Case Study



When a product's architecture absorbs regulation: Building artificial intelligence and privacy by design into a contactless patient monitoring system

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When developing medical systems driven by artificial intelligence (AI), companies must navigate technical, market, privacy, and regulatory expectations. And during this process, regulations are often treated as constraints to be managed after product development. The Swiss health tech company QUMEA took a different approach when it developed its contactless patient monitoring system: it included regulation as a design parameter from day one. This approach shaped the system's architecture, capabilities, and market position. Moreover, integrating regulatory considerations from the beginning of the development process helped the company better tackle subsequent regulatory requirements and commercial decisions. In this case study, QUMEA describes how it turned regulatory requirements into a competitive advantage by treating them as design inputs instead of hurdles.

Laying the foundation for a successful design concept

QUMEA originated in one of the most challenging clinical monitoring settings: hospital wards caring for patients with delirium. These patients are amongst the most vulnerable and face an elevated risk of falls, pressure injuries, and rapid clinical deterioration. Therefore, they require close, continuous observation. Yet conventional monitoring approaches are problematic in ways that go beyond resource constraints.

The default solution is to use patient sitters, who are staff assigned to observe a single patient around the clock. This solution is not only costly and hard to staff but, more importantly, the visible presence of an unknown observer can trigger or reinforce paranoid ideation, agitation, and distress in patients experiencing delirium, making this approach clinically counterproductive. More modern approaches such as camera-based and optical monitoring systems also pose this problem: patients may still be aware of the device. The resulting sense of being watched can exacerbate the very symptoms the monitoring is intended to manage. In addition, substantial data protection and ethical concerns accompany any system that captures imagery in a clinical environment, especially where patients are most vulnerable.

The fundamental question at QUMEA was whether contactless, continuous, and clinically meaningful patient monitoring could be achieved without these negative effects: without the system producing personal data and without the patient feeling observed. At its core, this question – posed even before the first line of code was written – was about what ethical AI in a clinical setting requires.

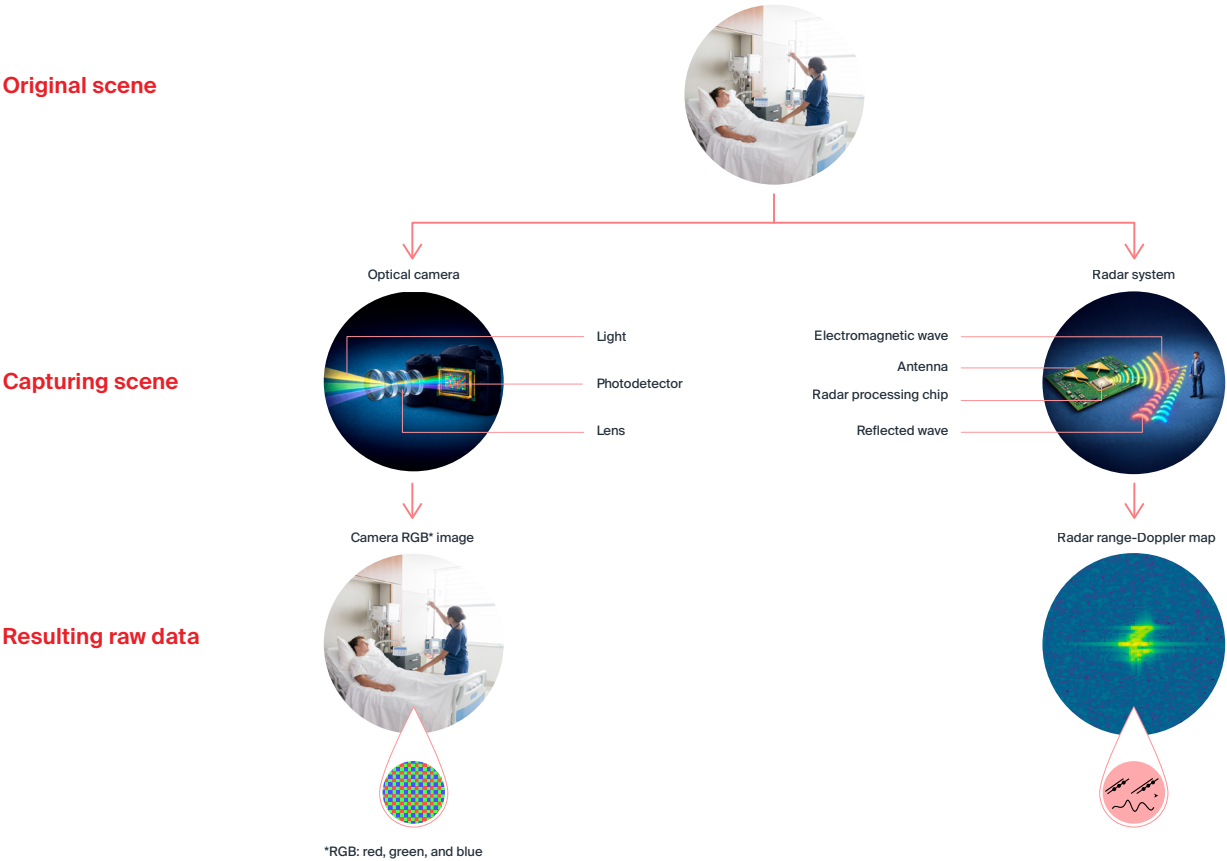
Radar: How one sensor shaped an entire system's architecture

To address the challenge of building a monitoring system that is intrinsically anonymous and that by design does not produce any personal data, QUMEA chose to use frequency-modulated continuous-wave (**FMCW**) radar sensors. FMCW radar transmits radio-frequency chirps and captures reflected signals across multiple antenna pairs. The raw output consists of range-Doppler tensors, which are complex numerical arrays that encode reflecting signal amplitude and phase of a moving surface across distance and velocity dimensions. These signals are not only extraordinarily rich in motion information but also, by their physical nature, intrinsically anonymous at the sensor level.

By design the sensors do not capture directly identifiable or biometric data or produce any data that enable identification without additional external context. This anonymity is not a processing choice; it is a measurement constraint. There is no path from the raw signal, which is physically limited by the wavelengths involved, back to a face or a body shape because that information is not captured in the first place. This gives radar a clear regulatory advantage over camera-based monitoring technology, which captures images and personal data so its raw data is not anonymous (see **Figure 1** for a comparison). This single architectural decision avoided structural compliance issues with the [General Data Protection Regulation \(GDPR\)](#), has enabled the company to build up a training dataset with over 25 million hours of patient movement recordings, and resulted in a proportionate [Medical Device Regulation \(MDR\)](#) Class I classification.

The problem of patients being aware of observation was addressed not only through the choice of technology (radar sensors do not have lenses or cameras that make them look like an observational device) but also through the sensor's physical design. Its small size and discreet form make the sensor's presence in a patient's room entirely unobtrusive, comparable to a smoke detector (see **Figure 2**).

Figure 1: Comparison of data capture in camera-based and radar-based technologies



Source: Adapted from [QUMEA AG](#) (2025), p.4¹

Figure 2: QUMEA's radar-based sensor



Source: [QUMEA AG](#)

From the sensor's initial application for fall prevention in delirium care, it has expanded to address a broader clinical need: continuous, objective insights into patients requiring close monitoring on general wards. The sensor is able to continuously record patients' mobility, activity levels, restlessness, reliable proxies to respiration, sleep, and emerging risks and can detect changes early, thus providing foresight. This results in more anticipation and less reaction. One example of such an application is the sensor's support of decubitus (pressure ulcers) prophylaxis.

AI: How a necessity became an opportunity

QUMEA added AI to its sensor not by choice but out of necessity. Range-Doppler tensors from multiple antenna pairs are high-dimensional, highly variable across patients and environments, and far too complex for rule-based interpretation at a clinical scale. This complexity in the sensing modality necessitated the use of AI to interpret the data.

Using AI created a productive dependency. Robust AI models demand large, diverse training datasets. Building such datasets in clinical environments requires a data architecture that can scale across institutions without prohibitive overhead for governance. Because QUMEA's sensor does not produce any personal data, it enabled exactly that. Today, QUMEA's models are trained on more than 25 million hours of movement recordings from patients' rooms. These training data were recorded by QUMEA sensors, accumulated in collaboration with clinical partners, and validated through structured feedback on system performance without the same consent and retention constraints that apply to identifiable data. The models' clinical performance was also independently assessed in a clinical study, which showed a significant decrease in falls of 49%.² In addition, QUMEA maintains a large, continually growing dataset of manually labelled and verified falls as well as other events against which its models are trained, validated, and tested. Rather than using a single general-purpose model, QUMEA operates several specialised models for specific tasks, such as determining whether a patient is alone. Moreover, many customers clinically validate the system in their own setting to prove the system's performance; this real-world data feeds

back into model development. Because all data are anonymous at source, neither this validation work nor the sensor's routine operation present the consent or data governance challenges that imaging-based approaches face. QUMEA relies on a dataset that is free from the complex consent frameworks, data minimisation constraints, and retention limitations that govern imaging-based alternatives.

These three elements – the sensor's architecture, the privacy properties it confers, and the AI capability it enables – were not the result of independent decisions made in sequence. Each determined the other: the use of radar in the sensor made anonymity structural, structural anonymity made the dataset possible, and the dataset made the AI clinically meaningful.

Turning regulatory compliance into a competitive advantage

For a multi-application clinical monitoring product, navigating the MDR begins with a fundamental question: for which applications is a product considered a medical device? The answer depends on an application's intended purpose, and the distinctions are consequential.

QUMEA's fall prevention application is intended to reduce the risk of injury – not to diagnose, monitor, or prevent a disease. Under the MDR, this places the sensor outside the medical device perimeter. This view is shared predominantly across the European Union (EU). QUMEA's supporting role in preventing pressure ulcers, by contrast, engages a clinical preventive function directly and is classified as a Class I medical device because it *supports* a clinical intervention without itself constituting that intervention.

Assessing an AI component in a clinical study context is a recurring challenge for medical device manufacturers: demonstrating algorithm performance, governing the training data, and providing the level of detail on the AI itself that regulators increasingly expect. Here too, the answer lies in the architecture. The regulated medical device function relies exclusively on deterministic machine learning rather than on generative or autonomously reasoning AI. By design, a given input yields the same output every time, so each output

remains a clinical signal, not a clinical decision. This reproducibility makes the models' behaviour traceable, testable, and auditable – properties that play a key role in clinical and regulatory assessments. Combined with data that are anonymous at source, it makes both the validation of the device and the ongoing governance of its data a structural property of the system rather than a procedural burden carried by approaches whose outputs are non-deterministic or derived from identifiable data.

Arriving at these distinctions required QUMEA to engage with the MDR text directly. Early in the sensor's development, QUMEA received widely divergent views from regulatory consultants. Rather than accepting that ambiguity, QUMEA read the regulation in full, developed its own classification rationale, and brought it to external advisors for validation. That investment produced not only a defensible classification but also added clarity to the product definition that has served every subsequent regulatory and commercial context.

Views diverged on the central question of whether fall detection constitutes a medical device at all. QUMEA's position – that preventing injury from falls (similar to a hospital handrail) is not a medical purpose and therefore falls outside the MDR – has been confirmed by external consultants and by the competent authorities in several countries, including Swissmedic and the Swedish Medical Products Agency. Under the EU's MDR (Art. 2(1)) and Switzerland's Medical Devices Ordinance (MedDO, Art. 3), the decisive factor is the manufacturer's intended purpose: prevention qualifies as a medical purpose only in relation to a disease, and a fall is not a disease. QUMEA's fall detection therefore remains outside the MDR irrespective of the patient population. A different classification would arise only from a genuinely medical claim, such as diagnosing or monitoring a condition.

When it comes to the GDPR, the system's architecture resolves compliance at the core: no personal data is produced, so data protection is a physical property of the system and not a procedural layer applied after the fact, as anonymisation or pseudonymisation procedures would be.

What QUMEA did not initially anticipate is how the MDR and GDPR – each demanding substantial effort from most medical device manufacturers – would combine into a competitive advantage. The sensor's true privacy-by-design architecture is, to QUMEA's knowledge, unique in the clinical monitoring market at scale.

Had a camera-based sensor been used, building a dataset of equivalent breadth under the same GDPR constraints would not have been possible. Deployment in the most privacy-sensitive settings, such as dementia care, psychiatric wards, palliative care, and even wet rooms, is substantially more straightforward when the system does not produce any data requiring protection. Because regulation was addressed at the level of the system's architecture, it became a source of product differentiation that is structurally difficult to replicate.

The evolving landscape of AI governance: The AI Act and proportionality

The EU's Artificial Intelligence Act (AI Act) now adds a horizontal governance layer alongside the MDR and GDPR. In June 2025, the EU's Medical Device Coordination Group (MDCG) clarified the interplay between regulations: a high-risk AI classification does not alter the MDR risk class, and documentation can be integrated into existing technical files.³ The principle of proportionality, which is central to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6(R3)) and increasingly important to AI governance more broadly, aligns with a system architecture built on anonymous sensing and human-in-the-loop design. Every output generated is a clinical signal, not a clinical decision, so the care team retains full decision-making authority. This satisfies the AI Act's human oversight requirements as naturally as it satisfies sound clinical practice.

Takeaway: Engaging with regulation can lead to innovative design decisions

QUMEA's development process – from a specific clinical need in delirium care to a radar-based AI foresight engine in use across multiple countries – was shaped at every stage by regulatory considerations. This was not because regulation constrained development, but because seriously engaging with it led to better design decisions. The sensor QUMEA chose, the AI it built, the classification it arrived at, and the product's market position are expressions of a single principle: the architecture of an AI medical device is inseparable from its regulatory architecture. In 2025, this approach – and the balance it achieves between AI capability, clinical utility, patient privacy, and regulatory clarity – was recognised with the Swiss Medical Technology Association's [Swiss Medtech Award](#), reflecting the broader community's recognition that using ethical AI in clinical settings represents a direction worth pursuing. For other teams navigating this space, the most important design question is no longer “How do we comply with regulations?” but “What product architecture inherently ensures compliance?”

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Regulatory News, Events, and Publications

Switzerland

Swiss Clinical Trial Organisation (SCTO)

Event

- **September 2026**

6th DIA|CH Symposium on Clinical Trials

The 6th DIA|CH Symposium on Clinical Trials took place on 29 and 30 September at Congress Innsbruck, Austria. Held every two years and organised jointly by the Koordinierungszentren für Klinische Studien (**KKS**) Netzwerk Österreich (in Austria), the Netzwerk der Koordinierungszentren für Klinische Studien (KKS Network) (in Germany), and the SCTO (in Switzerland), the symposium brings together professionals from across the healthcare sector. Key topics this year included the updated ICH Guideline for Good Clinical Practice E6(R3), current regulatory requirements, quality assurance, academic research, and digitalisation in clinical trials.

Source: [SCTO website \(News & Events, All News, DIA|CH Symposium on Clinical Trials 2026\)](#)

Event

- **June 2026**

SCTO Symposium 2026

Held on 2 June at the University Hospital Zurich (**USZ**) and organised jointly by the SCTO and the USZ's Clinical Trials Center (**CTC**), the SCTO Symposium 2026 brought together participants from academia, healthcare, industry, and regulatory bodies under the title "AI meets clinical research: Navigating regulatory, ethical, and legal frontiers". The programme covered artificial intelligence (**AI**) as it relates to trial design, data protection, pre-screening applications, and practical implementation, and the symposium featured keynote speakers from Swiss Federal Institute of Technology Zurich (**ETH Zurich**) and the ICH GCP E6(R3) Expert Working Group.

Source: [SCTO website \(News & Events, All Events, SCTO Symposium 2026\)](#)

Publication

- **March 2026**

SCTO's annual report for 2025

The SCTO published its [Annual Report 2025](#), which covers the first year of the 2025–2028 funding period and presents the past year's highlights from Switzerland's academic clinical research community.

Source: [SCTO website \(About Us, Annual Reports\)](#)

News

- **February 2026**

SCTO launches a new website and corporate identity

The SCTO unveiled its redesigned website together with a refreshed logo and corporate design. The organisation's previous websites ([sctoplatforms.ch](#) and [cr-careers.ch](#)) have been fully integrated into [www.scto.ch](#) so that tools, resources, platform information, and clinical research career content are now all available on a single platform.

Source: [SCTO website](#)

Event

- **January 2026**

SCTO Forum 2026

Held on 28 January in Bern, the SCTO Forum 2026 examined the future of decentralised clinical trials (**DCTs**) in Switzerland from regulatory, ethical, and practical perspectives. Speakers from Switzerland and Europe presented expert talks and case studies and shared practical experience. Their presentations were followed by a panel discussion on the role that DCTs will play in clinical research in Switzerland. The event brought together regulators, researchers, and industry representatives.

Source: [SCTO website \(News & Events, All Events, SCTO Forum 2026\)](#)

swissethics

Publications

● December 2025–March 2026

Updated position papers and guidance documents
swissethics published several updated position papers and guidance documents related to the submission and conduct of research projects in Switzerland.

- **Interpretation guide on representatives of foreign sponsors:** Role of representatives in Switzerland for sponsors based abroad. 15 December 2025. The Federal Office of Public Health, Swissmedic, and swissethics jointly agreed on this update in order to standardise assessment practice across authorities. (Available in [DE](#), [FR](#), [IT](#), and [EN](#))
- **Requirements for study protocols:** Requirements for study protocols according to the Human Research Act (HRA). Version 10.0, 18 January 2026. The requirements are based on the Clinical Trials Ordinance (**ClinO**), the Ordinance on Clinical Trials of Medical Devices (**ClinO-MD**), and the Human Research Ordinance (**HRO**). (Available in [EN](#))
- **Joint position paper with Swissmedic on decentralised clinical trials:** Decentralised clinical trials (DCTs) with medicinal products in Switzerland. Version 4.0, 9 March 2026. The appendices were renewed to reflect the updated recommendation paper on decentralised elements in clinical trials issued by the European Commission's Directorate-General for Health and Food Safety. (Available in [EN](#))

Source: [swissethics website \(Topics, Position papers\)](#)

News

● February 2026

New service finder for clinical and health research

The national Coordination Platform Clinical Research (**CPCR**) has launched the CPCR Service Finder. The tool was developed in collaboration with Swiss Biobanking, the Swiss Cancer Institute, the Swiss Clinical Trial Organisation, and the Swiss Personalized Health Network and received support and coordination assistance from the Swiss Academy of Medical Sciences. It allows researchers to browse the services offered by the main national research infrastructures supporting clinical and health research and to identify the relevant contact for a given need.

Source: [swissethics website \(News\)](#)

News

● November 2025

Information and consent for genomic research

swissethics has addressed the information and consent requirements that apply to genomic research using whole genome sequencing. General consent covers the reuse of genetic data in coded form, but swissethics notes that whole genome sequencing carried out as part of a research project represents a different dimension of genetics and therefore warrants separate consideration.

Source: [swissethics website \(News\)](#)

Publication

● March 2025

swissethics' annual report for 2025

swissethics released its annual report for 2025 (available in [DE](#) and [FR](#)), presenting the year's developments related to the coordination of the cantonal ethics committees and their collaboration with national stakeholders.

Source: [swissethics website \(Topics, Publications\)](#)

Swissmedic

News

• May 2026

Swissmedic clarifies requirements for clinical trials with multiple sponsors

Swissmedic clarified how clinical trials of medicinal products and advanced therapy medicinal products (**ATMPs**) with more than one sponsor are to be implemented. All sponsor obligations under the ClinO and the rules of good clinical practice set out in ClinO (Art. 5) and ICH GCP E6(R3) must be fully ensured, including the following:

- The allocation of roles and distribution of responsibilities must be documented and contractually defined.
- The arrangement must be disclosed transparently to Swissmedic and the competent ethics committees.
- The sponsors are jointly and severally liable and must provide corresponding proof of insurance.
- All sponsors must be named explicitly in the written informed consent documentation.
- Analogous measures apply to clinical investigations of medical devices and performance studies of in vitro diagnostic medical devices involving several sponsors.

Source: [Swissmedic website \(Latest News, General communications\)](#)

News

• May 2026

Ethics committees join Swissmedic's fast-track pilot project

As of May 2026, applications for clinical trials with medicinal products of categories B and C that have received advance confirmation of accelerated review by Swissmedic are also evaluated in an accelerated manner by the responsible ethics committee. Sponsors need to indicate their request for a Swissmedic fast-track procedure when submitting the project via the Business Administration System for Ethics Committees (**BASEC**) portal. The harmonised procedure expands the pilot project launched by Swissmedic in July 2025 and is intended to shorten the time to first enrolment in authorised trials.

Source: [Swissmedic website \(Human medicines, Clinical trials, Clinical trials on medicinal products\)](#)

News

• November 2025–April 2026

Swiss public consultations on draft ICH guidelines

Swissmedic ran national public consultations on three draft guidelines from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**) and then forwarded comments to the ICH secretariat. The consultation on Guideline E20 (Adaptive Designs for Clinical Trials) closed on 30 November 2025, the consultation on Guideline Q3E (Guideline for Extractables and Leachables) closed on 18 December 2025, and the consultation on Guideline E22 (General Considerations for Patient Preference Studies) closed on 12 April 2026.

Source: [Swissmedic website \(About us, International collaboration, Multilateral co-operation, ICH\)](#)

Europe

European Medicines Agency (EMA)

News

• June 2026

ICH E6(R3) Annex 2 adopted in the EU

Annex 2 of the ICH E6(R3) Guideline for Good Clinical Practice was adopted by ICH on 3 June 2026 and by the Committee for Medicinal Products for Human Use (CHMP) on 25 June 2026. It comes into effect in the EU on 15 January 2027. Annex 2 covers pragmatic clinical trials, decentralised clinical trials, and trials that incorporate real-world data sources. It should be read together with the guideline's overarching principles and Annex 1, which came into effect on 23 July 2025.

Source: [EMA website \(ICH E6 Good clinical practice – Scientific guideline\)](#)

News

• May 2026

First progress report on 2030 clinical trial targets

The EMA reported on progress made towards the clinical trial targets the EU set for 2030. Nineteen multinational clinical trials have been authorised in addition to the historical average, and 40.5% of all clinical trials recruit participants within 200 days.

Source: [EMA website \(News, EU tracks progress towards 2030 clinical trial targets\)](#)

Publication

• May 2026

ACT EU workplan for 2026–2027

The Accelerating Clinical Trials in the European Union (ACT EU) initiative published its [workplan for 2026–2027](#) together with a revised set of objectives. The workplan is informed by EU legislative and policy initiatives shaping the clinical trials environment, including the proposed European Biotech Act, the Clinical Research Investment Plan under the Strategy for European Life Sciences, and the EU4Health initiatives. The workplan identifies the following new focus areas for ACT EU: strengthening meaningful patient involvement across the clinical trial life cycle, using clinical trial data to improve access and foster more inclusive trials, and supporting the timely submission of clinical trial results.

Source: [ACT EU website \(Newsroom, News, ACT EU workplan for 2026–2027 & updated objectives published\)](#)

Publication

• March 2026

Draft guidance on clinical trials during public health emergencies

ACT EU released a draft guidance document on the conduct of clinical trials during public health emergencies in the EU. It is the first EU guidance document on this topic that reflects the current legislative framework as well as the guidelines developed by ICH after the COVID-19 pandemic. The guidance document proposes mechanisms to accelerate the authorisation of new trials and the approval of modifications to ongoing trials where these relate directly to an emergency, and it encourages sponsors to seek scientific advice from the Emergency Task Force.

Source: [EMA website \(News, New guidance on the conduct of clinical trials during public health emergencies in the EU\)](#)

Publication

• January 2026

Joint EMA and FDA guiding principles on good AI practice in drug development

The EMA and the US Food and Drug Administration (FDA) jointly published [Guiding Principles of Good AI Practice in Drug Development](#) on 14 January 2026. This set of ten high-level principles covers the use of artificial intelligence to generate or analyse evidence across the non-clinical, clinical, post-marketing, and manufacturing phases. The principles address risk-based management, data governance, life cycle monitoring (including monitoring for data drift), transparency, and human oversight. They are not binding requirements but are intended to inform sponsors, applicants, and authorisation holders and to lay the foundation for future AI-specific guidance in both the EU and the US.

Source: [FDA website \(About FDA, FDA Organization, CDER, Artificial Intelligence for Drug Development\)](#)

News

● November 2025

Improved scientific advice for medicines addressing public health threats

The EMA introduced a new approach to providing scientific advice that brings clinical trial and ethics expertise together in order to accelerate the development of medicines needed ahead of or during public health emergencies. Under the new process, developers of medicines within the scope of EMA's Emergency Task Force (**ETF**) can request combined advice from the EMA as well as clinical trial and ethics experts at the national level.

Source: [EMA website \(News, Improved scientific advice for medicines for public health threats including antimicrobial resistance\)](#)

Publications

● October 2025

New recommendations for clinical trial sponsors

ACT EU published new documents to help sponsors implement the EU's Clinical Trials Regulation (**CTR**). Sponsors preparing clinical trial applications can now consult a [recommendation paper on the issues most frequently identified during the assessment of Part I and Part II](#), which is intended to help them address common concerns in advance and shorten the time to trial initiation. An updated version of the [recommendation paper on decentralised elements in clinical trials](#) is also available, now containing a statement on cross-border trials and a revised overview of national provisions. The European Commission's Clinical Trials Coordination and Advisory Group (**CTAG**) issued [revised recommendations on the use of auxiliary medicinal products in clinical trials](#), effective from 1 December 2025, with additional clarification and examples.

Source: [ACT EU website \(Newsroom, News, Recommendations for clinical trial sponsors\)](#)

International

Council for International Organizations of Medical Sciences (CIOMS)

Publication

- **June 2026**

Updated CIOMS Glossary of ICH Terms and Definitions

CIOMS released version 10 of its [Glossary of ICH Terms and Definitions](#), dated 15 June 2026. The glossary compiles key terminology used across the guidelines issued by ICH and supports a harmonised interpretation of regulatory language. CIOMS updates the glossary twice a year, in mid-June and mid-December.

Source: [CIOMS website \(Publications\)](#) (glossary doi: [10.56759/effb6868](#))

Publication

- **November 2025**

New report on artificial intelligence in pharmacovigilance

The CIOMS Working Group XIV published a new [report](#) addressing the use of artificial intelligence in pharmacovigilance, a field at the intersection of pharmacovigilance, computer science, regulation, law, medicine, and the social sciences. Rather than providing technical guidance, the report sets out guiding principles and a general framework of good practice for developing and using AI in pharmacovigilance, which are structured around a risk-based approach. The report is addressed to regulators, industry stakeholders, academic researchers, clinicians, patients, and technology vendors.

Source: [CIOMS website \(Publications, Pharmacovigilance\)](#) (report doi: [10.56759/cdob6397](#))

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Publication

- **June 2026**

Consolidated ICH E6(R3) Guideline for Good Clinical Practice

A [consolidated version](#) of the ICH E6(R3) Guideline for Good Clinical Practice, which brings together the overarching principles, Annex 1, and Annex 2, was published on 16 June 2026. The recently adopted Annex 2 sets out how GCP principles may be applied across a range of trial designs and data sources, including decentralised elements, pragmatic elements, and real-world data sources, and is intended to be read together with the principles and Annex 1. Annex 2 will remain available on ICH's website as a separate document until December 2026.

Source: [ICH website \(Work Products, ICH Guidelines, Efficacy Guidelines\)](#)

World Health Organization (WHO)

Publication

- **February 2026**

Review of clinical trials and environmental sustainability

The WHO published a [review](#) examining environmental sustainability throughout the clinical trial life cycle. Developed in the context of implementing the World Health Assembly's resolution WHA75.8 on strengthening clinical trials, the publication reviews key considerations for climate change mitigation and adaptation and explores approaches to reducing the environmental impact of clinical trial activities.

Source: [WHO \(Publications, Overview, Clinical trials and environmental sustainability: review of key considerations to develop climate change mitigation and adaptation strategies\)](#)

Publication

- **November 2025**

Updated guidance on developing medical device policies

The WHO published the [second edition](#) of its guidance on developing national medical device policies. The updated guidance covers regulatory frameworks as well as health technology assessment and health technology management, and it introduces medical device nomenclature. It is intended to help countries to develop comprehensive policies addressing medical devices throughout their life cycle.

Source: [WHO website \(Publications, Overview, Development of medical device policies, 2nd ed.\)](#)

Publication

- **October 2025**

WHO technical report on setting research priorities for child health

The WHO published a [technical report](#) to address evidence gaps in paediatric clinical trials, particularly for children aged 0–9 years. The document identifies priority research questions and is intended to guide coordinated research and investment to strengthen the evidence base for child health policies, guidelines, and programmes.

Source: [WHO website \(Publications, Overview, The future of paediatric clinical trials – setting research priorities for child health\)](#)

Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation	GDPR	General Data Protection Regulation (EU)
ACT EU	Accelerating Clinical Trials in the European Union	GenAI	generative artificial intelligence
AI	artificial intelligence	HIS	hospital information system
AI Act	Artificial Intelligence Act (EU)	HMA	Heads of Medicines Agencies
AIM-MASH	AI-based measurement of metabolic dysfunction-associated steatohepatitis	HRA	Federal Act on Research Involving Human Beings
ATMP	advanced therapy medicinal product	HRO	Ordinance on Human Research with the Exception of Clinical Trials
BASEC	Business Administration System for Ethics Committees	ICD	intra-cardiac defibrillator
BSI	British Standards Institution	ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
CE	Conformité Européenne	ICH GCP	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice
CHMP	Committee for Medicinal Products for Human Use (EMA)	IEC	International Electrotechnical Commission
CIOMS	Council for International Organizations of Medical Sciences	IG-NB	German Notified Bodies Alliance for Medical Devices
ClinO	Ordinance on Clinical Trials in Human Research	IMDRF	International Medical Device Regulators Forum
ClinO-MD	Ordinance on Clinical Trials of Medical Devices	ISO	International Organization for Standardization
CPCR	Coordination Platform Clinical Research	IvDO	Ordinance on In Vitro Diagnostic Medical Devices
CRC	clinical research centre	IVDR	In Vitro Diagnostic Medical Devices Regulation (EU)
CTAG	Clinical Trials Coordination and Advisory Group (European Commission)	KKS	Koordinierungszentrum für Klinische Studien
CTCG	Clinical Trials Coordination Group (HMA)	LLM	large language model
CTEG	Clinical Trials Expert Group (European Commission)	MASH	metabolic dysfunction-associated steatohepatitis
CTR	Clinical Trials Regulation (EU)	MDCG	Medical Device Coordination Group
DCT	decentralised clinical trial	MDR	Medical Device Regulation (EU)
DHT	digital health technology	MDSW	medical device software
DTUA	data transfer and use agreement	MedDO	Medical Devices Ordinance
EHDS	European Health Data Space	PROCOVA	Prognostic Covariate Adjustment (methodology)
EHR	electronic health record	RA Platform	Regulatory Affairs Platform (SCTO)
EMA	European Medicines Agency	RCT	randomised controlled trial
ETF	Emergency Task Force (EMA)	SCTO	Swiss Clinical Trial Organisation
ETH Zurich	Swiss Federal Institute of Technology Zurich	SPHN	Swiss Personalized Health Network
EU	European Union	Team-NB	The European Association of Medical devices Notified Bodies
EUPATI CH	European Patients' Academy on Therapeutic Innovation Switzerland	USZ	University Hospital Zurich
FADP	Federal Act on Data Protection	WHO	World Health Organization
FDA	US Food and Drug Administration		
FMCW	frequency-modulated continuous-wave (radar)		
GCP IWG	Good Clinical Practice Inspectors Working Group (EMA)		

Regulatory Affairs Watch

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Sources of information

- We gather news on regulatory topics related to human research.
- We regularly read newsletters and visit the websites of relevant sources, including regulatory authorities in Switzerland, Europe, and the United States; ICH and WHO; Swiss academic organisations and health associations; and professional associations.
- Additionally, we review major clinical research journals.

SCTO Regulatory Affairs Platform

The Regulatory Affairs Platform is one of the Swiss Clinical Trial Organisation's eight topic-based SCTO Platforms that promote excellence in clinical research in Switzerland. Find out more about the Regulatory Affairs Platform and read past issues of *Regulatory Affairs Watch* on the [SCTO's website](#).

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