

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