REGULATORY NEWS, EVENTS, AND PUBLICATIONS

SWITZERLAND

Coordination Office for Human Research (Kofam)

PUBLICATION

● **SEPTEMBER 2024**

Report on ethics committees' activities in 2023

Kofam has published its summary report Activities of the Research Ethics Committees 2023. This annual publication informs the public about operations and developments within Switzerland's ethics committees, thus fulfilling the Human Research Act's (**HRA's**) requirement for transparency in human research practices.

Source: FOPH website (Tasks of the FOPH: information and coordination)

Federal Council

NEWS

● **JULY 2024**

Amendments to HRA ordinances

The Federal Council approved modifications to HRA ordinances on 7 June 2024. The modifications aim to strengthen the protection of research participants and improve the regulatory framework for researchers. The amended ordinances entered into force on 1 November 2024, except for the provisions relating to transparency, which will enter into force on 1 March 2025.

Source: Federal Council website (Press releases), available in DE, FR, and IT

NEWS

● **MAY 2024**

Gender disparities in health care and research

The Federal Council adopted a report emphasising the need to address gender disparities in health care and medical research. Swissmedic has been mandated to evaluate and integrate sex and gender factors into clinical research guidelines and communities. Additionally, the Federal Office of Public Health (**FOPH**) and the State Secretariat for Education, Research and Innovation (**SERI**) will review and propose measures to ensure gender considerations are part of healthcare professionals' training. The responsible federal offices are expected to implement research-related actions and report back to the Federal Council by the end of 2029.

Source: Federal Council website (Press releases), available in DE, FR, and IT

Federal Office of Public Health (FOPH)

EVENT

● **NOVEMBER 2024**

Symposium: Ten Years of the Human Research Act – past, present and future

2024 marks the 10th anniversary of the Human Research Act. Together with its four implementing ordinances, the HRA established a uniform framework and has greatly improved transparency and safety standards in human research. To commemorate this milestone, the FOPH hosted a symposium on 22 November 2024, during which experts discussed the HRA's past achievements, current impact, and future direction.

Source: Kofam website (Research on humans, Symposium)

Swiss Clinical Trial Organisation (SCTO)

EVENT

● **JANUARY 2025**

SCTO Forum 2025

The SCTO Forum 2025 will take place on 29 January in Bern and will focus on the latest revisions to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6(R3)). The forum will discuss how these updates modernise and improve global clinical practices, emphasising flexibility, efficiency, and data integrity. More information will be available soon on the SCTO's website.

Source: SCTO website (Forum 2025)

EVENT

● **SEPTEMBER 2024**

D|A|CH Symposium für klinische Prüfungen

A delegation from the SCTO Executive Office participated in the 2024 D|A|CH Symposium für klinische Prüfungen in Berlin. The event featured engaging and insightful presentations and provided a valuable opportunity for clinical research communities across Switzerland, Austria, and Germany to connect.

Source: D|A|CH website, available in DE

EVENT

● **JUNE 2024**

SCTO Symposium: Working towards efficient clinical data-driven research in Switzerland

The SCTO Symposium 2024 was held on June 11 in Lausanne. The event addressed the growing volume and complexity of data in clinical research, emphasising the need for efficient data management and sharing. Discussions included challenges faced by clinical researchers, such as regulatory requirements, IT infrastructure needs, and data governance.

Source: SCTO website (Symposium 2024)

swissethics

PUBLICATION

● **SEPTEMBER 2024**

Report on human research in Switzerland in 2023

swissethics has released its statistical report Human Research in Switzerland 2023. The report provides descriptive data on research projects submitted to and approved by the ethics committees under the HRA. The report supports transparency in research and informs stakeholders on trends and activities in ethical review.

Source: swissethics website (Publications)

NEWS

● **SEPTEMBER 2024**

Updated templates

swissethics updated its templates to ensure compliance with the revised HRA ordinances. The updated templates are available on swissethics' website.

Source: swissethics website (Templates / Checklists)

PUBLICATION

● **JANUARY 2024**

swissethics' 2023 annual report

In its 2023 annual report, swissethics highlights a year of significant initiatives, including expanded training initiatives for members of ethics committees, strengthened partnerships with federal authorities, and its progress in harmonising ethical standards across cantons.

Source: swissethics website (Publications), report available in DE and FR

Swissmedic

NEWS

● **NOVEMBER 2024**

Implementation of revised HRA ordinances

As of 1 November 2024, the revised HRA ordinances have officially come into effect. The provisions on transparency will enter into force on 1 March 2025. Information on submission procedures, updated guidelines, and specific requirements can be found on Swissmedic's website.

Source: Swissmedic (Implementation of new ordinances)

NEWS

● **SEPTEMBER 2024**

New forms and information sheet for combined studies

New forms and an updated information sheet were introduced on 1 September to facilitate submissions to Swissmedic for combined studies. Additional details and access to the forms can be found on Swissmedic's website under the "Clinical Trials, Combined studies" section.

Source: Swissmedic website (Announcements, Combined studies)

NEWS

● **JULY 2024**

Fee reduction for non-commercially funded clinical trials

On 1 July, Swissmedic introduced an 80% fee reduction for processing applications for non-commercially funded clinical trials. This initiative aims to reinforce Switzerland's position as a research hub while maintaining the quality and assessment standards for submission. More information on how to apply for a fee reduction for a clinical investigation or a performance study can be found on Swissmedic's website.

Source: Swissmedic website (Announcements, Academic trials)

NEWS

● **JUNE 2024**

Changes to declaration of goods for the export of medicinal products

On 17 June, Swissmedic announced updates to the declaration process for exporting medicinal products, including those for clinical trials and narcotics. These changes, effective on 4 November 2024, require exporters to provide additional information (e.g. establishment licence number and licence holder details) in the Federal Office for Customs and Border Security's (**FOCBS's**) Passar system. The transition to the Passar system, which began on 17 March 2024, will be completed on 1 January 2026.

Source: Swissmedic website (General communications, Changes to declaration of goods)

PUBLICATION

● **JUNE 2024**

Swissmedic's 2023 annual report

On 7 June, the Federal Council approved the Swissmedic Annual Report 2023, which covers Swissmedic's performance, its finances, and its strategic initiatives for 2023–2026. The report also highlights the agency's achievements; for example, the World Health Organization (**WHO**) has designated Swissmedic as a WHO Listed Authority (**WLA**), an accomplishment that solidifies Swissmedic's role as a key player in global health regulation.

Source: Swissmedic website (Annual Report 2023)

EUROPE

European Medicines Agency (EMA)

NEWS

● **JANUARY 2025**

End of the CTR transition period

The transition period for the EU's Clinical Trials Regulation (**CTR**) is reaching to end. All EU clinical trials are required to be moved to the Clinical Trials Information System (**CTIS**) by 30 January 2025. This shift aims to streamline clinical trial processes across Europe, thus enhancing the region's appeal for clinical research.

Source: EMA website (Clinical Trials Regulation)

PUBLICATION

● **SEPTEMBER 2025**

Guidance on the use of large language models

EMA and the Heads of Medicines Agency (**HMA**) have published Guiding Principles on the Use of Large Language Models in Regulatory Science and for Medicines Regulatory Activities. Aimed at enhancing tasks such as documentation and administrative support, these guidelines emphasise safe and responsible use and cover data input, critical thinking, and staff training.

Source: EMA website (News, Harnessing AI in medicines regulation)

NEWS

● **JUNE 2025**

Revised CTIS transparency rules

New CTIS transparency rules aimed at balancing public health protection and sponsor interests in EU medical research took effect on 18 June. The revised rules clarify confidentiality protections, thus ensuring that key clinical trial information relevant to patients is published promptly while keeping CTIS user-friendly.

Source: EMA website (News, Revised transparency rules for the EU CTIS)

NEWS

● **MARCH 2024**

DARWIN EU updates

On 6 March, the EMA announced an expansion of the Data Analysis and Real World Interrogation Network's (**DARWIN EU's**) capacity to conduct real-world data (**RWD**) studies across Europe. DARWIN EU now has access to data from approximately 130 million patients.

Source: EMA website (News, DARWIN EU)

INTERNATIONAL

Council for International Organizations of Medical Sciences (CIOMS)

PUBLICATION

- **MAY 2024**

Real-World Data and Real-World Evidence in Regulatory Decision-Making

CIOMS has released a report exploring the role of real-world data (**RWD**) and real-world evidence (**RWE**) in regulatory and healthcare decision making.

Source: CIOMS website (Publications) (report doi: 10.56759/kfxh6213)

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

PUBLICATION

- **AUGUST 2024**

ICH adopts E11A guideline for paediatric drug development

Initially released for consultation in April 2022, the ICH has finalised its Pediatric Extrapolation E11A guideline. The guideline creates a standardised framework for using adult drug trial data to support paediatric drug approvals.

Source: ICH website (Efficacy Guidelines)

US Food and Drug Administration (FDA)

PUBLICATION

- **SEPTEMBER 2024**

Guidance on decentralised clinical trials

The FDA has released its final guidance document Conducting Clinical Trials with Decentralized Elements, which was initially released as a draft in May 2023. This guidance offers recommendations for sponsors and investigators on implementing decentralised approaches that allow trial-related activities to occur remotely.

Source: FDA website (Conducting Clinical Trials With Decentralized Elements)

World Health Organization (WHO)

PUBLICATION

- **SEPTEMBER 2024**

Best practices for clinical trials

The WHO's Guidance for Best Practices for Clinical Trials aims to enhance the quality, efficiency, and ethical standards of clinical trials globally. It offers recommendations to strengthen clinical research ecosystems, focusing on patient safety, scientific rigor, and community engagement. In addition, it emphasises the importance of conducting sustainable, high-quality clinical trials in order to ensure equitable access to health innovations worldwide.

Source: WHO website (Publications, Guidance for best practices for clinical trials)

World Medical Association (WMA)

PUBLICATION

- **OCTOBER 2024**

Revision of the Declaration of Helsinki

The WMA has adopted the 2024 revision of the Declar ation of Helsinki, which reinforces ethical standards in human clinical research. The new version emphasises greater safeguards for vulnerable populations, improves transparency in clinical trials, and promotes fairness in research practices.

Source: WMA website (WMA Declaration of Helsinki)

PUBLICATIONS

- **Ohmann C et al. (2024) Survey by ECRIN about National Registries for Observational Studies and Sharing of Individual Participant Data** (version v1 dated 25 March 2024).
doi: 10.5281/zenodo.10868392

  This collaborative survey by the European Clinical Research Infrastructure Network (**ECRIN**), featuring contributions from the SCTO, explores national registries for observational studies and the sharing of individual participant data. The report aims to highlight current practices and address challenges in data sharing and to advance transparency and accessibility in clinical research.

- **Ormond KE et al. (2024) What are the bottlenecks to health data sharing in Switzerland? An interview study.** Swiss Medical Weekly (154):3538.
doi: 10.57187/s.3538

  This interview study, co-authored by members of the SCTO's Regulatory Affairs Platform, explores obstacles to health data sharing in Switzerland. The study was conducted in collaboration with several organisations, including the Health and Policy Lab at ETH Zurich, the Swiss Personalized Health Network (**SPHN**), the Swiss Biobanking Platform (**SBP**), and the Bern Center for Precision Medicine (**BCPM**), and delves into key challenges and possible improvements related to sharing health data.