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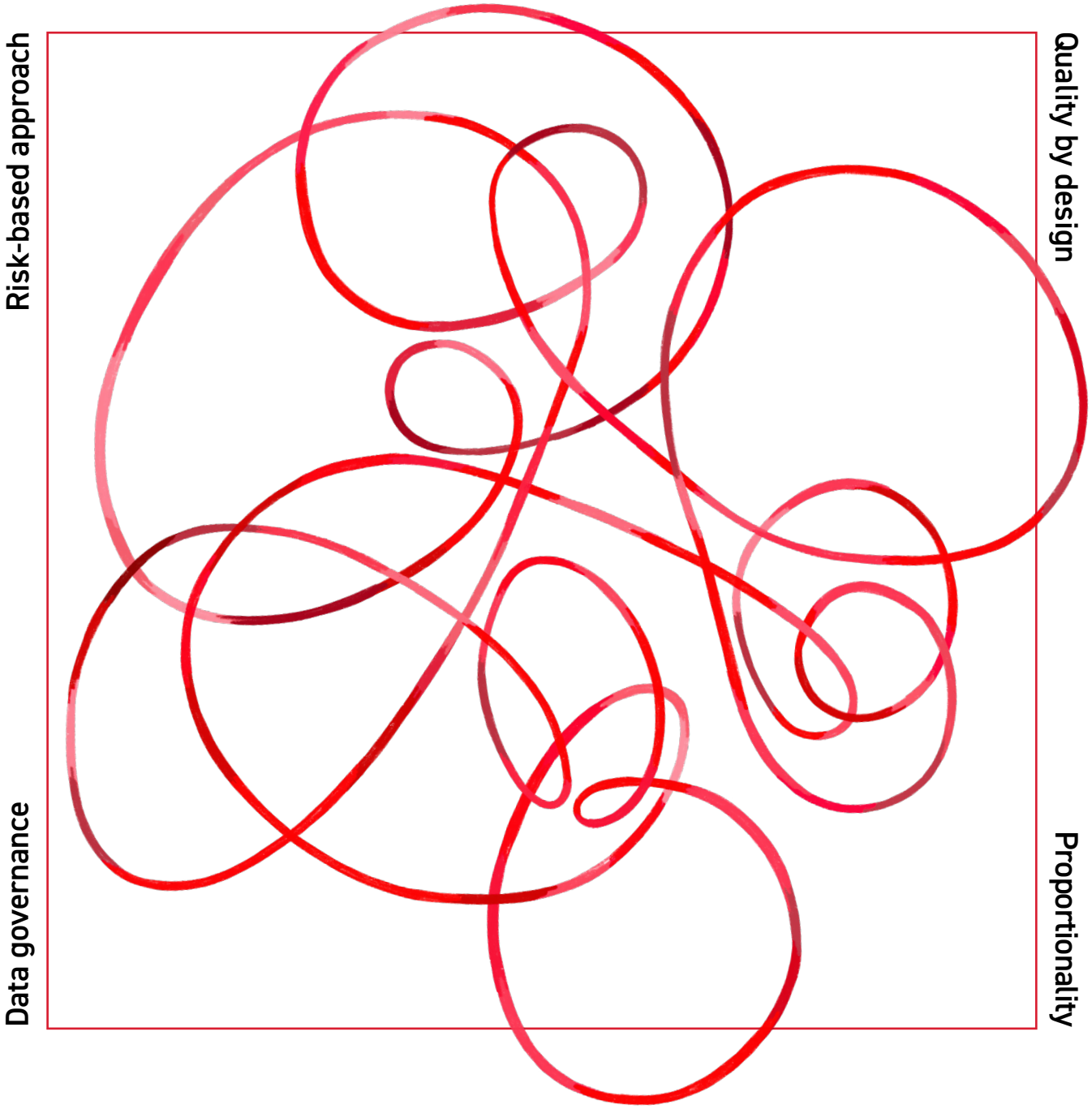
ICH GCP E6(R3):
How it impacts clinical research in Switzerland



EDITORIAL

FACING THE WINDS OF CHANGE: WHAT DOES ICH GCP E6(R3) MEAN FOR CLINICAL RESEARCH IN SWITZERLAND?

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The winds of change are literally blowing through the clinical research landscape. With the third version of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (**ICH GCP E6(R3)**) now formally adopted and in effect since 15 August 2025 in Switzerland (Annex 2 is to be adopted soon and will come into effect no earlier than 2026), the clinical research community is undergoing a period of rapid transition – and a bit of turbulence.

The revised ICH GCP E6(R3) represents a shift in how we approach quality, risk, oversight, and data governance. This shift is also evident in the revisions to the ordinances of Switzerland's Human Research Act (**HRA**) that took effect in two steps (at the beginning of November 2024 and in March 2025 for changes that apply to transparency provisions) and the revisions to the World Medical Association's Declaration of Helsinki that were adopted in October 2024. All these regulatory changes reflect an effort to align national and international regulations with the rapidly changing realities of and latest developments in clinical research. The overarching aim of this regulatory shift is to promote a more participant-centred, flexible, and fit-for-purpose approach to clinical research that results in higher transparency and accountability and is better suited for advances in technology.

The Regulatory Affairs Platform at the Swiss Clinical Trial Organisation (**SCTO**) has been following these regulatory changes very closely. Moreover, we have been advocating for a favourable regulatory environment that supports academic research by expressing our opinions in public consultations and face-to-face discussions with regulatory authorities. In October 2024, we sat together with Swissmedic and swissethics at a roundtable meeting to discuss the implications of the modifications to the HRA's ordinances. We also attended the annual SCTO Forum in January 2025, where we discussed the practical implications of ICH GCP E6(R3) with national and international experts.

This issue of *Regulatory Affairs Watch* focuses on ICH GCP E6(R3) and its impact on clinical research in Switzerland and contains the following articles:

- **DEEP DIVE:** In our Deep Dive article, regulatory affairs specialist Fanny Muet looks at the history of ICH GCP E6 and the rationale behind its latest revision (R3). She also considers the implications of the third version for investigators, sponsors, and data governance and highlights some key takeaways.

- **FEEDBACK FROM:** Clinical research professionals are grappling with how to implement ICH GCP E6(R3) changes in practice. To help them navigate these changes in Switzerland, *RA Watch*'s editorial team compiled a series of questions for swissethics. In our Feedback From article, swissethics answers our questions and explores the ethical and operational implications of the most important ICH GCP E6(R3) changes.

- **VIEWS AND OPINIONS:** One significant addition to ICH GCP E6(R3) is its new section dedicated to data governance. In our Views and Opinions article, database administrator Fady Fares goes through the new data governance section and offers his perspective on data management and how academic teams can adapt their practices to the updated regulation.

In order to keep up with the rapid pace of these regulatory changes, we are publishing this issue of *RA Watch* as an Express Edition, with a leaner format and a tighter publication schedule. We came up with the Express Edition format so we can respond more quickly to emerging topics that require immediate attention and also provide our readers with clarity and expertise when they most need it. Depending on a topic's importance, future issues of *RA Watch* will be published either in our standard, long-form format or our new express format.

This is also our tenth issue of *Regulatory Affairs Watch* – a milestone in the evolution of the publication. From its start in 2018 as a newsletter providing updates on regulatory topics related to human research, *RA Watch* has grown into a longer publication, with each issue focusing on a current topic in clinical research and its impact in Switzerland. The publication has expanded to include a deep dive into the issue's topic, feedback from the authorities, views and opinions from a variety of stakeholders in clinical research, and updates on regulatory news, events, and publications. Depending on the topic, we also include a case study.

To mark this *RA Watch* milestone, we have created a special cover for our tenth issue and freshened up the design inside. We would also like to use this occasion to thank the editorial teams who came before us and contributed their expertise, energy, and time to the continuation and growth of *RA Watch*. Without them, we would not be where we are now!

We hope you enjoy reading *RA Watch 10* in its Express Edition format – and that it helps you and the rest of our community better understand, navigate, and even soar through the current winds of regulatory change.

DEEP DIVE

RETHINKING GOOD CLINICAL PRACTICE: A SHIFT FROM GUIDELINES TO GOVERNANCE IN ICH GCP E6(R3)

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The core international guideline on good clinical practice is the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6). While other ICH guidelines (such as ICH E8 and ICH E11) offer complementary guidance for clinical trials or specific populations, ICH GCP E6 remains the primary and authoritative GCP framework. Since ICH GCP E6 was first published in 1996, clinical trials have become much more complex and technology has advanced considerably. The third version (R3) not only responds to these developments, but it also represents a fundamental shift from one-size-fits-all guidelines to a more nuanced and adaptive governance model. This article looks into the background of ICH GCP E6 and the driving factors of the third version, lists key updates, and dives into the impacts of the revision, especially on investigators, sponsors, and data governance. The article concludes with a key takeaway: clinical research professionals will need to remain flexible and keep a proactive mindset as they put ICH GCP E6(R3) into practice.

THE EVOLUTION OF ICH GCP E6

Historical background: Ethical principles and guidelines for medical research

Historically, good clinical practices have been developed in response to ethical violations in medical research. In fact, it was unethical experiments carried out on humans during World War II that led to the first international guidance document addressing medical research ethics, the Nuremberg Code, in 1947. This code established ten fundamental ethical principles. The first – and most important – principle identifies informed consent as an absolute prerequisite for conducting research involving human beings.[1] Building on this foundation, the World Medical Association (**WMA**) adopted the Declaration of Helsinki in 1964 as a statement of ethical principles for medical research involving human participants, which introduced more comprehensive ethical principles.[2] Following the Tuskegee syphilis study scandal in the United States, in which rural black participants were denied treatment in order to avoid interrupting the study, the Belmont Report was issued in 1979.[3] The report further strengthened the ethical regulatory framework in the United States and introduced three core principles that continue to shape ethical research practices today: respect for persons, beneficence, and justice.

ICH GCP E6 guideline: Creation and evolution

The regulatory authorities in Europe, Japan, and the United States were key players in establishing the International Conference on Harmonisation (**ICH**) in 1990. Now called the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, ICH continues to pursue its aim to bring regulatory authorities and the pharmaceutical industry together in order to develop recommendations for better harmonising the interpretation and implementation of technical guidelines and requirements for pharmaceutical product development and registration. Throughout the 1990s, ICH issued formal guidance on the topics of safety, quality, and efficacy, which reflect the three criteria forming the basis for the approval and authorisation of new drugs.

ICH published its Good Clinical Practice Guideline (**ICH GCP**) in 1996, which is listed as ICH's sixth clinical efficacy guideline (E6). ICH GCP E6 set an international standard for designing, conducting, recording, and reporting clinical trials involving human participants. It outlines the responsibilities of sponsors, investigators, and other stakeholders to safeguard participants' rights, safety, and well-being while also ensuring the integrity and reliability of trial data.

ICH GCP E6 focuses exclusively on clinical trials and has been revised two times since its creation:

1. **ICH GCP E6(R1):** Published in **1996**, the initial version established unified international standards to ensure the ethical and scientific integrity of clinical trials.
2. **ICH GCP E6(R2):** Published in **2016**, the first revision introduced a risk-based quality management approach and stricter data integrity requirements to enhance trial efficiency and oversight.
3. **ICH GCP E6(R3):** Initiated in **2021** and published in **2025** (Annex 2 will be adopted later and should enter into force in the EU and Switzerland at the beginning of 2026 at the earliest), this revision aims to improve the flexibility and proportionality of trials as well as the integration of digital tools and decentralised clinical trial methodology.

ICH GCP E6(R3): Reasons for the revision

In the three decades since ICH GCP E6 was first drafted, the growing complexity of clinical trials – driven by technological advances, larger data volumes, and a greater involvement of service providers – has highlighted the need for regular updates to the guideline. The second version ICH GCP E6(R2) was released in 2016, and even though it addressed electronic data sources and risk management strategies, ICH recognised that additional updates would be necessary as clinical trials continue to evolve.

The update from ICH GCP E6(R2) to ICH GCP E6(R3) was driven by several key factors, including **incorporating technological innovations** that enhance data collection (electronic data sources) into clinical trials and managing these innovations. The revised version also aims to **improve trial flexibility and adaptability** in order to be able to accommodate diverse types of trial designs and thus keep pace with scientific and methodological advancements. The adoption of **a risk-based approach** emphasises a risk-balanced approach to ensure that clinical trials are managed efficiently by focusing resources on the most critical aspects while maintaining high standards of quality and participant safety. ICH GCP E6(R3) promotes **a proportionate approach** to trial conduct, encouraging fit-for-purpose solutions tailored to specific contexts. Furthermore, the revision **strengthens the roles and responsibilities of sponsors and investigators**, which enhances accountability and ensures more effective trial management. Additionally, the revision ensures **better alignment with other guidelines**, in particular with recent updates to related guidelines such as the General Considerations for Clinical Studies Guideline (**ICH E8(R1)**). Adopted in October 2021, the ICH E8(R1) guideline provides foundational principles for designing robust and meaningful trials across various methodologies in a broader and more general sense. It introduces quality by design (**QbD**) principles and prioritises **critical-to-quality** (**CtQ**) **factors** early in trial planning in order to enhance data integrity and patient safety. ICH GCP E6(R3), on the other hand, is more practical and operational, focusing on the execution, management, and oversight of trials in compliance with GCP. The latest revision of ICH GCP E6 also reinforces **transparency** by requiring trial registration in a publicly accessible database and the reporting of results and by providing enhanced guidance to strengthen the informed consent process. ICH GCP E6(R3) represents a modernisation of GCP principles that support innovation in clinical trial design, technology, and operational strategies.

According to the European Medicines Agency (**EMA**), the new structure of ICH GCP E6(R3) enhances clarity and readability: the Principles section outlines overarching principles and objectives, Annex 1 covers traditional interventional clinical trials, and Annex 2 provides additional considerations for non-traditional interventional clinical trials, such as pragmatic and decentralised clinical trials as well as trials that incorporate real-world data sources.[4]

The final versions of ICH GCP E6(R3)'s Part II (Principles of ICH GCP) and Part III (Annex 1) were adopted on 6 January 2025; they entered into force in the EU on 23 July 2025 and in Switzerland on 15 August 2025.[5] In the time between ICH GCP E6(R3)'s adoption by ICH and its entry into force in Switzerland, stakeholders had the opportunity to analyse the updated guideline and prepare to implement it.

Annex 2 is expected to be finalised later in 2025 and will provide additional considerations tailored to specific types of trials, such as those involving pragmatic elements, real-world data (**RWD**), or decentralised elements. While the core principles of GCP will remain applicable, Annex 2 aims to offer practical guidance for adapting these principles in more complex and innovative trial settings. Moving forward, Annex 2 will likely play a key role in shaping the implementation of GCP across a broader spectrum of clinical research designs.

KEY UPDATES IN ICH GCP E6(R3)

Part II (Principles of ICH GCP) of ICH GCP E6(R3) opens with an expanded and detailed description of GCP principles and focuses particularly on innovative clinical trial designs and emerging technologies. These updated principles reflect the evolution of clinical research and aim to align ICH GCP E6 with the realities of contemporary clinical research. Among the updates are the following two new principles:

- **Principle 7: "Clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected and that avoids unnecessary burden on participants and investigators."**[6] This principle introduces a risk-proportionate approach, advocating for streamlined processes that prioritise both participant safety and data relevance while minimising undue burden.

- **Principle 10: "Roles and responsibilities in clinical trials should be clear and documented appropriately."**[7] This new principle reinforces the need to clearly define and document the responsibilities of all parties involved in a trial in order to ensure transparency, accountability, and operational efficiency.

These new principles aim to enhance trial efficiency, promote clarity, and support participant-centred practices across all stages of clinical research. Beyond these specific additions, ICH GCP E6(R3) places greater emphasis on several concepts, including increased participant involvement through a more patient-centred approach, the quality by design concept, increased transparency, and the integration of digital technologies. The addition of a specific section on data governance illustrates its evolving emphasis on maintaining data integrity, the strengthening of digital oversight mechanisms, and the modernisation of how clinical trials are conducted. Two critical questions that arise are how these conceptual shifts translate into operational practice and what tangible impacts they will have on different stakeholders.

IMPACT OF ICH GCP E6(R3) REVISION

Impact on investigators

This section includes the main information gathered during a workshop on ICH GCP E6(R3) held by Accelerating Clinical Trials in the European Union (**ACT EU**) in February 2025.

Qualifications and training requirements

During the workshop, it was emphasised that while evidence of investigators' qualifications must be provided, there is flexibility in how this documentation is presented (see ICH GCP E6(R3), Annex 1, Section 2.1.1). Training for trial staff should be tailored to the tasks delegated to them, especially when tasks extend beyond their standard experience or background. The guideline now acknowledges that in addition to physicians, other qualified healthcare professionals may contribute to participants' trial-related medical care if it aligns with their usual practice and local regulations. Furthermore, if delegated activities are part of routine clinical care, it may not be required to document them (see Annex 1, Section 2.3.3). Another important point highlighted in the workshop was that the investigator's level of oversight should be proportionate to the nature of the delegated activities, the significance of the data involved, and potential risks to participant safety and data integrity. In the end, it is essential to document delegated activities in a way that is appropriate for the given situation. Regardless of how this is done, it is ultimately the investigator who remains responsible for all delegated tasks (see Annex 1, Section 2.3.1).

Consent

In terms of how to obtain consent, ICH GCP E6(R3) acknowledges that trial information and consent discussions may be communicated in various formats, including images, videos, and other interactive tools alongside traditional text-based consent forms (see Annex 1, Section 2.8.1.c). Regardless of the method used, the information provided to participants must remain as clear and concise as possible, use simple language, and avoid unnecessary volume and complexity (see Annex 1, Section 2.8.1.b). The informed consent process must be properly documented, either on paper or electronically, using a signed and dated informed consent form. When appropriate, this process may be carried out remotely. The updated guideline also considers the need for re-consent, which should be evaluated if new information becomes available that may affect a participant's willingness to continue taking part in the trial. If re-consent is deemed necessary, the updated consent materials must clearly highlight the new information (see Annex 1, Section 2.8.2). A specific process for consent should be considered and anticipated when a minor reaches the age of majority during their participation in the study (see Annex 1, Section 2.8.12).

Early withdrawal: Data handling and participant follow-up

ICH GCP E6(R3) includes new clarifications related to data handling and participant follow-up. If a participant withdraws from a trial early, the new ICH GCP E6(R3) advises researchers to put appropriate procedures in place to ensure follow-up and to avoid any unnecessary loss of data that have already been collected. These procedures must be in line with regulatory requirements (see Annex 1, Section 2.9.1).

Investigational product management

ICH GCP E6(R3) clarifies that sponsors may facilitate certain aspects of investigational product (**IP**) management, for example by providing forms, offering technical solutions, or coordinating the distribution of the IP to trial participants (see Annex 1, Section 2.10.1). The level of oversight required by investigators should be proportionate to several factors, including the IP's characteristics, the complexity and route of administration, the extent of safety data available, and whether the product is already marketed (see Annex 1, Section 2.10.3).

Participant safety

In order to safeguard participants' safety and well-being, ICH GCP E6(R3) emphasises that – right from the beginning of the trial – investigators must be prepared and able to perform unblinding without delay in the event of an emergency (see Annex 1, Section 2.11). In addition, ICH GCP E6(R3) defines a new safety reporting period, stating that unfavourable medical events occurring before IP administration (e.g. during screening) should be reported to the sponsor in accordance with the protocol (see Annex 1, Section 2.7.2.a). This reinforces the importance of early vigilance and protocol guidance from the screening phase onward while also highlighting the need for a flexible approach throughout a trial.

Impact on sponsors

With regard to sponsors, the (R3) revision emphasises the importance of designing trials based on sufficient safety and efficacy data, integrating a risk-based quality management approach, involving a broad range of stakeholders (including patients), and ensuring the design is operationally feasible (see Annex 1, Section 3.1). The guideline's quality management section has been further developed to provide more detail and to reinforce the emphasis on quality management and a risk-based approach (see Annex 1, Section 3.10). The quality assurance and quality control section (Annex 1, Section 3.11) has been further developed as well, highlighting a risk-based monitoring approach, more flexible monitoring strategies, monitor qualifications, comprehensive monitoring documentation, and the introduction of centralised monitoring as an additional practice option (see Annex 1, Section 3.11.4). The guideline now clarifies that agreements with service providers and other parties should be established before starting activities (see Annex 1, Section 3.6.1) and updated if there are significant changes to the activities transferred (see Annex 1, Section 3.6.2).

In terms of oversight, the sponsor is expected to apply oversight measures that are proportionate to a trial's complexity and risks and to implement appropriate quality assurance and control processes for both investigators and service providers. Something new in ICH GCP E6(R3) is that in addition to preparing a full clinical study report, sponsors are expected to provide investigators with a summary of the trial results. For blinded trials, once unblinding and all analyses are done, sponsors should give each investigator the treatment allocation of their participants and a brief overview of the overall trial outcomes. The trial summary intended for participants should be non-technical, understandable to a lay person, and non-promotional (see Annex 1, Section 3.17.2.c). When it is relevant and trial participants wish to receive the information, investigators are expected to inform them about the trial results and treatment received (see Annex 1, Section 2.9.3).

Data governance

The guideline's new section on data governance (Annex 1, Section 4) applies to both investigators and sponsors and provides comprehensive guidance on data management responsibilities, including computerised systems and critical processes such as randomisation. While this new data governance section does not introduce any fundamentally new concepts, it clarifies and reinforces existing expectations.

ICH GCP E6(R3)'s new data governance section highlights the importance of ensuring that the computerised system used is suitable for the trial context. Furthermore, it provides a more structured approach to ensure data integrity, security, and reliability. Because the new section offers clearer guidance on the use of digital tools, it will help sponsors and investigators maintain high standards throughout the full data life cycle. For a detailed discussion of the new data governance section, read the **VIEWS AND OPINIONS** article on p. 15.

CONCLUSION

ICH GCP E6(R3) fundamentally reassesses the concept of good clinical practice. Rather than adhering to strict, one-size-fits-all guidelines, the revised framework embraces a governance-based model that is more nuanced and adaptive. This paradigm shift reflects the recognition that effective oversight of clinical research requires context-sensitive decision-making, proportionate risk management, and a clear definition of responsibilities for all stakeholders. Beyond a simple structural change, the transition from a rigid framework to a dynamic governance model in ICH GCP E6(R3) embodies the adoption of a new, inherently proactive mindset in the conception and application of good clinical practice.

A fundamental principle that emerges in ICH GCP E6(R3) is proportionality. For investigators, this means team training can now focus on trial-specific activities beyond routine clinical practice. Oversight should be tailored to the importance of the collected data and risks to participant safety. Activities that are part of routine clinical care may no longer require formal delegation documentation. Adopting a balanced approach appears to be an effective way to focus resources on the most critical elements of a trial without compromising on quality or participant safety.

With regard to sponsors, ICH GCP E6(R3) introduces higher expectations around evidence-based trial design, proportionate oversight, and risk-based quality management. It also places greater emphasis on transparency and communication with investigators and participants, notably by requiring lay summaries and individual treatment allocations. Altogether, the latest revision reflects a more flexible, accountable, and participant-centred approach to clinical trial governance.

From both the investigator's and the sponsor's perspective, the main takeaway of the changes made to ICH GCP E6 is to remain flexible and keep a proactive mindset as they apply proportionality and a risk-based approach throughout the entire study process – from a trial's design to the final report. It is essential to safeguard participants' safety and their rights while ensuring data integrity and reliability, which can be effectively accomplished by embracing risk-based strategies and proportionality.

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FEEDBACK FROM
SWISSETHICS

swissethics

Schweizerische Vereinigung der Forschungsethikkommissionen
Association suisse des Commissions d'éthique de la recherche
Associazione svizzera delle Commissioni etiche della ricerca
Swiss Association of Research Ethics Committees

KEY QUESTIONS ON THE LASTEST REVISION OF ICH GCP E6 WITH ANSWERS AND INSIGHTS FROM SWISSETHICS

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The long-anticipated revised version (R3) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6) introduces important changes to clinical research, especially in academic settings. Now that most of the revised guideline has entered into force in Switzerland, clinical research professionals are grappling with what these changes mean in practice. In order to help the research community navigate these developments, *Regulatory Affairs Watch*'s editorial team compiled a series of questions and turned to swissethics for its perspective. This exchange highlights how core principles of ICH GCP E6(R3) are interpreted and applied in Switzerland as well as how evolving requirements intersect with institutional realities. Moreover, swissethics addresses practical considerations such as documentation, investigator qualifications, and the use of interactive tools to enhance participant understanding. This article aims to provide clinical research professionals with a clear, actionable overview of swissethics' key expectations following the revision of ICH GCP E6.

Q&A: INSIGHTS FROM SWISSETHICS

Since it was first published in 1996, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP E6) has evolved significantly. From swissethics' perspective, how has Switzerland's interpretation and application of ICH GCP principles changed over time, particularly in the context of academic research?

The evolution of ICH GCP E6 reflects the growing maturity of the clinical research ecosystem, particularly with regard to how academic research is conducted and governed. Whereas it once focused heavily on procedural compliance (working instructions and checklists were at the core of each decision and step taken), the current version ICH GCP E6(R3) now emphasises principles-based, risk-proportionate, and participant-centred practices. In response to this shift in practices over the past several years, academic institutions have had to build or enhance their research infrastructures, develop training programmes, and implement quality management systems. These changes have not only improved compliance but also transformed the design, conduct, and oversight of academic research.

The latest ICH GCP E6 revision (R3) has generated considerable discussion within the research community; however, no broad legal amendments to Swiss legislation are planned (except for a reference update to the Clinical Trials Ordinance). Does swissethics consider Switzerland's existing framework both sufficient and modern enough to accommodate ICH GCP E6(R3) principles? Or does ICH GCP E6(R3) represent a broader shift that investigators should treat as more than a technical update?

That is a question that would require a 10-page essay to answer adequately. The answer here can only be very generic. The latest revision of ICH GCP E6 is not a revolution but rather a necessity, because the way clinical trials are conducted has changed significantly in recent years. The evolution of ICH GCP E6 now reflects these changes. It reflects the maturing of the clinical research ecosystem (the growing complexity of trial designs, the increased use of new technologies, the greater volume of digital data, and the increasing involvement of external service providers in the conduct of clinical trials). It also reflects a shift from a reactive to a proactive mindset, as clinical research has moved from a compliance-focused approach to one that is principles-based, risk-adapted, and patient-centred.

It is noteworthy that the Human Research Act (**HRA**) came into force while version (R1) of ICH GCP E6 was the applicable guideline. It is therefore necessary that those who are currently working on the revision of the HRA integrate these shifts in approach into the law.

ICH GCP E6(R3) places a strong emphasis on risk and quality management requirements, and it calls for trial processes to be proportionate to risk while minimising participant burden. How should academic sponsors reflect these elements in study documents (protocol, risk assessment summary, central quality management plan, etc.), and what level of detail will demonstrate adequacy?

There is clearly no scale to refer to and no measurable threshold to demonstrate adequacy. Each trial requires a case-by-case approach, which must be rethought and re-evaluated throughout the entire trial period. The ideal solution is found through consultation between the parties involved. Investigators and sponsors may involve patients, patient advocacy groups, and healthcare professionals to help address risk and quality management during the conception and design of a clinical trial, while it is being conducted, and in the reporting phase. While investigators may know more about an intervention's risks, who knows more about minimising participant burden than the participants themselves? Greater patient and public involvement in research is desired not only in the revised ICH GCP E6(R3) but also in the updated SPIRIT 2025 Statement (Standard Protocol Items: Recommendations for Interventional Trials). Furthermore, ICH GCP E6(R3) introduces changes that help reduce the administrative burden when the level of risk is lower (this approach is reminiscent of the categorisation of studies into "risk" categories in the HRA's ordinances) and empower investigators to provide a rationale instead of merely declaring that a requirement has been "fulfilled".

ICH GCP E6(R3) promotes a quality by design (QbD) framework, which encourages proactive risk identification and mitigation throughout a trial's life cycle. Some academics are concerned that these concepts are more industry-oriented and may not be suitable for the realities of academic research. How does swissethics view the feasibility of implementing QbD in academic settings? And what would be a proportionate way for non-commercial sponsors to adopt these principles?

The quality by design (**QbD**) concept is introduced in Part II (Principles of ICH GCP), Principle 6, of ICH GCP E6(R3) and can be summarised as the identification of critical to quality factors in order to prevent errors that could compromise patient safety and data reliability. In ICH GCP E6(R3), quality is not viewed as a rigid or absolute standard but rather as the degree to which a trial is fit for its intended purpose. While clinical trials conducted by commercial sponsors are often more complex and may carry higher levels of risk compared to academic trials, it is important that academic investigators and non-commercial sponsors do not simply replicate the quality by design approaches used in the commercial sector. Instead, they should focus on identifying and addressing the critical and relevant risk factors specific to the design and context of their own studies in order to enhance the likelihood of successfully achieving their trial objectives.

This latest revised version (R3) increases sponsors' responsibilities for centralised quality oversight. For investigator-initiated clinical trials, what documentation will research ethics committees look for and how does this differ from current expectations?

Quality management in ICH GCP E6(R3) emphasises proactive risk-based approaches and continuous improvement over a reactive risk-based approach. In practice, this shift from a reactive to a proactive approach has been underway for years, and ICH GCP E6(R3) now legitimises it. Therefore, there will be no significant changes to the trial documentation to be submitted to the research ethics committee (which is regulated by the Clinical Trials Ordinance (**ClinO**), Annex 3) but rather an update of some chapters in the trial protocol template with more specific and detailed instructions.

ICH GCP E6(R3) requires investigators to be qualified in terms of education, training, and experience. Besides traditional CVs, what evidence does swissethics consider acceptable to demonstrate an investigator's suitability?

ICH GCP E6(R3)'s revised Section 2.1 on investigators' qualifications clarifies expectations on evidence for qualifications, allowing more flexibility in terms of documentation compared to Section 4.1 in the former version (R2). Given that the ClinO's Article 6, which specifies the required professional qualifications of investigators, and Annex 3, which lists the application documents to be submitted to the research ethics committee, will not be amended accordingly, ethics committees will continue assessing investigators' qualifications in accordance with Article 6 and Annex 3 of the ClinO. The assessment will mainly be done on the basis of CVs and GCP certificates. However, ethics committees always have the right to request further information and documentation if they deem it necessary.

In addition to e-consent, ICH GCP E6(R3) encourages using interactive tools to improve participants' understanding of trial processes. What is swissethics' view on the ethical value on such tools? Does it foresee research ethics committees encouraging their use in certain studies?

swissethics has always and continues to promote an informed consent process that is simple and clear. The use of interactive e-tools – when they are adapted to match participant characteristics and take into consideration the context, the specific design of a trial, and the risks and benefits to inform participants (or their legal representatives) and obtain informed consent – is not only welcome but becomes a necessity when it enables a simple and clear informed consent process. After all, comprehensibility is an ethical dimension. swissethics would like to take this opportunity to remind researchers that using e-tools sets high standards for quality and data security and increases the responsibilities of investigators and sponsors alike.

ICH GCP E6(R3) just came into effect in Switzerland in summer 2025. Will ongoing academic trials be granted a transition period to continue under the existing process? What timelines should investigators follow for training on the updated ICH GCP?

Ongoing clinical trials can continue unchanged. Ethics committees and Swissmedic already supervise, in complementary ways, the conduct of clinical trials and their compliance with the legal framework, directly intervening when necessary. This supervision is being strengthened by now requiring investigators and sponsors to include the status of their clinical trials in the annual report they submit to the ethics committee, an obligation that came into force with the revised HRA ordinances last November 2024.

In February this year, swissethics asked all GCP course providers to update their courses to reflect the revised HRA ordinances, the revised Declaration of Helsinki of October 2024, and the revised ICH GCP E6(R3), Annex 1, of January 2025. It is the responsibility of each individual researcher to ensure that they meet the requirements set out in Article 6 of the ClinO and Sections 2.1 and 2.3.2 of ICH GCP E6(R3), regardless of any deadlines for training that swissethics may or may not decide to set in the future. Nevertheless, ethics committees may always ask an investigator to retake a GCP course or attend a GCP refresher course if they believe his or her knowledge is not adequate to conduct a clinical trial.

VIEWS AND OPINIONS
DATA GOVERNANCE

DATA GOVERNANCE IN ICH GCP E6(R3)

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The latest revision of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (**ICH GCP E6(R3)**) brings significant changes compared to the previous revision (R2). Among the most impactful additions is its new data governance section, which expands on the topic's pre-existing sparse coverage. The guideline now clearly states the requirements for collecting, managing, and protecting data throughout their life cycle. This article addresses topics within each subsection of this new data governance section in light of current processes: establishing a contingency plan, defining electronic case report form (**eCRF**) specifications, training users and defining their access rights, using an audit trail, safegarding blinded information, transferring data between computerised systems, cleaning and validating data, archiving and destroying data, and other topics. It also presents advantages and challenges of the newly added section and makes some recommendations about how to incorporate it into in real-life practices.

DATA GOVERNANCE IN ICH GCP E6(R3)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**) has long set the global standard for good clinical practice (**GCP**). The latest revision of its GCP guideline, ICH GCP E6(R3), brings significant changes compared to the previous revision (R2), and it focuses on participant safety, risk-based approaches, and updated technology and data management. This latest update reflects the growing complexity of data ecosystems, the rise of decentralised and digital trials, and the need for robust, risk-based oversight.

Among the most impactful additions is the data governance section (see ICH GCP E6(R3), Annex 1, Section 4), which expands on the scattered mentions in ICH GCP E6(R2) about data integrity, electronic systems, and documentation. The guideline now clearly states the requirements for collecting, managing, and protecting data throughout a trial's life cycle. While these aspects are briefly mentioned under investigator responsibilities (see ICH GCP E6(R2), Section 4.9, and ICH GCP E6(R3), Section 2.12) and sponsor responsibilities (see ICH GCP E6(R2), Section 5.5, and ICH GCP E6(R3), Section 3.16), the new data governance section of ICH GCP E6(R3) provides more detailed guidance (see ICH GCP E6(R3), Section 4).

The new data governance section is a response to several converging trends: (1) the digital transformation of clinical trials, including electronic data capture (**EDC**), central data monitoring, and wearable devices; (2) the decentralisation of clinical trials, which distribute data collection across multiple sites and platforms; (3) increased regulatory scrutiny of data integrity and traceability; and (4) cybersecurity threats and the need for robust data protection mechanisms. Data are not just a by-product of clinical studies but the foundation upon which regulatory decisions, patient safety, and scientific validity rest.

The evolution of ICH GCP E6(R3) also aligns with broader legislation, such as the European Union's General Data Protection Regulation (**GDPR**) and Switzerland's recently revised Data Protection Act (**FADP**). One example is data destruction, which is introduced in Section 4.2.8 of ICH GCP E6(R3) and can be found in the GDPR (Article 5, paragraph 1, letter e) and FADP (Article 5, letter d). Another example is about data security and confidentiality requirements, which are addressed in Section 4.3.3 of ICH GCP E6(R3) and can also be found in the GDPR (Article 5, paragraph 1, letter f and Article 32) and FADP (Article 8).

If other detailed guidance based on good clinical practice (e.g. IT/data management standards published by the European Clinical Research Infrastructure Network (**ECRIN**)) is already being followed, the new data governance section of the ICH GCP E6(R3) should not come as a surprise and, in most cases, should already be implemented. Many of ICH GCP E6(R3)'s requirements are already described in different trial-related documentation such as the protocol, data management plan, and/or statistical analysis plan defined for a trial.

The following paragraphs examine each subsection of the data governance section in ICH GCP E6(R3) alongside current processes.

Section 4.1: Safeguard blinding in data governance

Maintaining blinding throughout a trial is crucial, including during data access and analysis. Roles for accessing unblinded information should be clearly defined. Computerised systems typically manage access rights, and tools like secuTrial® software (the EDC system currently used by members of the Swiss Clinical Trial Organisation (**SCTO**)) include specific user rights for emergency unblinding. An unblinding event is included in an EDC audit trail and adequately documented in the trial master file (**TMF**) and/or investigator site file (**ISF**).

Section 4.2: Data life cycle elements

Procedures that cover the entire data life cycle, from capture to destruction, and that require data to be accurate, complete, and attributable are mandated in Section 4.2. The automatic validation of data and verification of manual transcriptions are essential to ensure integrity. Specifications for the electronic case report form (**eCRF**) include the list of metadata to be collected and the definition of data quality checks that make it possible to ensure data accuracy. Guidelines for data collection and entry should be defined to avoid errors in essential activities. Traceable metadata, such as user rights and data changes, that are managed by an integrated audit trail function and individual logins definition are required to prevent unauthorised access.

An ongoing, risk-based review of data and metadata is necessary throughout the trial and is adjusted based on experience. Corrections to erroneous data must be prompt and justified, and deviations are to be reported when needed. Data transfers should be based on clear mapping definition between variables, and they should be validated for integrity, documented, and adequately checked. Each action taken to finalise the data and prepare it for analysis is discussed, confirmed, and documented. Data cleaning is usually performed directly through the EDC of the clinical data management system (**CDMS**) via queries addressed to data entry operators and is validated by the monitor, project manager, investigator, and/or data manager.

Once finalised, data must be archived in long-term, readable formats such as text files and kept protected from unauthorised access and alteration by using controlled access storage and/or a password protected file. Even though each access to data should be traceable, it is not always the case in real life. Data may be destroyed when they are no longer required by law, but this is rarely done and/or documented in practice.

Section 4.3: Computerised systems

Sponsors and investigators are required to ensure that the computerised systems they use are fit for purpose and comply with applicable legal obligations. The aim of using such systems and how to address the regulatory requirements should be carefully considered in the early stages of clinical trial planning and system set-up. Guidelines and instructions should be provided for all users collecting, handling, or processing data in a computerised system to avoid any misunderstandings and ensure reproducibility. End users must be adequately trained according to their tasks in the clinical study, and training logs must be maintained.

ICH GCP E6(R3) provisions require that sponsors and investigators implement technical and organisational measures to protect data from unauthorised access, loss, or corruption. In practice, data security is maintained through firewall rules, backups, updates, system monitoring, and password policies. Suspicious activities should be blocked to prevent security breaches. Any technical problems should be handled in a timely manner either automatically (i.e. a predefined script) or by sending an email to the system administrator requesting further investigation. Computerised systems must be validated before they are used, periodically once in use, and after updates to ensure that their functionality, reliability, and accuracy meet all requirements and that stored data are preserved. At the trial level, a list of required functions should be established and tested in order to validate that the system is fit for purpose.

Trial-specific developments (e.g. definition of variables and forms) need approval, such as approval from an ethics committee, before they can be implemented, released, or activated. Contingency plans, including data backup or exports, should be established to prevent critical data loss or system inaccessibility. Support for issue resolution and documentation is usually provided by the clinical study's project manager in coordination with the data manager (e.g. rectify incorrect implementation or project settings) or the system administrator (e.g. fix technical issues). The workflow for account attribution should be clearly defined in order to prevent unauthorised access. The project manager should review each request to create or modify access according to the user's delegated tasks and then forward confirmed requests to the data manager for implementation.

While the ICH GCP E6(R3)'s new data governance framework provides a robust foundation, it may also introduce several challenges: small-sized sponsors and sites may struggle with the technical and financial demands of compliance, different jurisdictions may interpret and implement data governance requirements differently, and organisations involved in clinical trials must invest in training staff and updating standard operating procedures (**SOPs**) to align with the new expectations. On the other hand, ICH GCP E6(R3) is grounded on the proportionality principle, which allows sponsors and investigators to tailor their data governance approach to the complexity and risk level of their clinical study.

CONCLUSION

Clinical research is heading towards a dynamic future of interconnected systems. In this context, ICH GCP E6(R3) provides clear instructions for researchers by integrating technology and data governance into the core of good clinical practice. At the same time, it promotes compliant, efficient, and transparent clinical studies that are focused on participants' needs and are built on quality design principles. The updated guideline also empowers stakeholders to conduct clinical studies that are not only scientifically rigorous but also ethically sound and operationally resilient. Clinical research must continue to uphold its high scientific, ethical, and operational standards, even as technology continues to develop – often at a faster pace than guidelines. Moreover, because data collection and management are becoming increasingly complex and the volume of data involved continues to grow, advanced management and governance is required.

Are we prepared to take on data responsibility by cultivating a culture of proactive data stewardship and to leverage technological innovation by investing in more compliant systems? Or are our processes still trying to catch up?

REGULATORY NEWS, EVENTS, AND PUBLICATIONS
SWITZERLAND

Federal Office of Public Health (FOPH)

NEWS

- **MARCH 2025**

FOPH launches new portal for human research

The new Human Research Switzerland (**HumRes**) platform has replaced kofam.ch and the Swiss National Clinical Trials Portal (**SNCTP**) as the public source of information on clinical research in Switzerland from 1 March 2025. All existing and new trials will be assigned a new HumRes number. The SNCTP numbers of trials published up to 28 February 2025 in the SNCTP remain valid and can continue to be used on HumRes for trial searches.

Source: FOPH website (New platform for human research in Switzerland)

Swiss Clinical Trial Organisation (SCTO)

EVENT

- **JUNE 2025**

SCTO Symposium 2025

Held on 3 June in Basel, the SCTO Symposium 2025 brought together over 160 participants to discuss how to better integrate clinical research into routine medical care. Key topics included adapting study designs to real-world needs, strengthening ethical and regulatory frameworks, improving data infrastructures, and fostering collaboration between research and healthcare systems.

Source: SCTO website (SCTO Symposium 2025)

PUBLICATION

- **MAY 2025**

SCTO's annual report for 2024

The SCTO published its 2024 Annual Report, marking its successful completion of the 2021–2024 funding period and highlighting its progress in strengthening clinical research. Key achievements include expanding methodological and regulatory resources, enhancing education, and improving patient and public involvement in clinical research. The SCTO has also received renewed funding for 2025–2028 and reaffirmed its commitment to innovation, collaboration, and excellence.

Source: SCTO website (Annual Report)

swissethics

PUBLICATION

- **MARCH 2025**

swissethics' annual report for 2024

swissethics released its annual report for 2024 (available in DE and FR), outlining developments related to the revised Human Research Ordinance (**HRO**), coordination between ethics committees, and collaboration with national stakeholders. It also highlighted ongoing improvements to the Business Administration System for Ethics Committees (**BASEC**) platform and the publication of new position papers on topics including electronic informed consent, gender, and artificial intelligence.

Source: swissethics website (Topics, Publications)

PUBLICATIONS

- **OCTOBER 2024–SEPTEMBER 2025**

Updated and new position papers and guidance documents

swissethics published several updated and new position papers and guidance documents addressing emerging issues in human research.

- **Guidance document on genetics in human research:** Guidance on genetics in human research. Version 2.0, 7 October 2024 (Available in DE, FR, and IT)
- **Guidance document on artificial intelligence (AI) and human research:** Artificial intelligence (AI) and research involving human beings: Issues to consider when submitting a project to a research ethics committee. Version 1.0, 14 April 2025 (Available in EN)
- **Joint position paper with Swissmedic on decentralised clinical trials (DCTs):** Decentralised clinical trials (DCTs) with medicinal products in Switzerland. Version 3.2, 15 August 2025 (Available in EN)
- **Joint guidance document with Swissmedic on first-in-human (FIH)/early phase I clinical trials:** General aspects to consider for FIH/early phase I clinical trials with medicinal products. Version 2.0, 1 September 2025 (Available in EN)

Source: swissethics website (Topics, Position papers)

SWITZERLAND

Swissmedic

NEWS

- **JULY 2025**

Swissmedic launches public consultations on ICH Guidelines E20 and E21

Swissmedic has launched public consultations in Switzerland on drafts of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (**ICH's**) Guideline E20 (Adaptive Designs for Clinical Trials) and Guideline E21 (Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials). Stakeholders are invited to submit comments to Swissmedic by 30 November 2025 and 15 September 2025 respectively.

Source: Swissmedic website (About us, International collaboration, Multilateral co-operation with international organisations, ICH)

NEWS

- **JUNE 2025**

Swissmedic introduces fast-track processing for clinical trial applications

Swissmedic launched a pilot project in July 2025 introducing a fast-track procedure for clinical trials applications. This procedure allows for an accelerated review of trial involving innovative treatments with high medical need, particularly in early phase studies.

Source: Swissmedic website (General Communications)

PUBLICATION

- **JUNE 2025**

Swissmedic's annual report for 2024

Swissmedic published its Annual Report 2024 highlighting the agency's key achievements, including the launch of its own cloud infrastructure, several new databases, and its continued focus on accelerating access to innovative treatments. The agency processed over 10,000 authorisation applications and applications for variations and approved 144 clinical trials in 2024.

Source: Swissmedic website (Publications, Annual Report, Annual Report 2024)

PUBLICATION

- **APRIL 2025**

Swissmedic's updated position paper on the use of real-world evidence

Swissmedic released version 3.0 of its position paper on the use of real-world evidence (**RWE**) in medicinal product authorisations. The document outlines key scientific, legal, and regulatory considerations for integrating RWE into decision-making processes while reaffirming that current Swiss law still requires clinical trial data to be compliant with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (**ICH GCP**).

Source: Swissmedic website (Human Medicine, Authorisations, Real World Evidence (RWE))

EUROPE

European Medicines Agency (EMA)

NEWS

• **MAY 2025**

EU regulatory agencies publish a workplan on data and AI

EMA and the Heads of Medicines Agencies (**HMA**) released a joint workplan outlining how the European regulatory network will coordinate its approach to data and artificial intelligence (**AI**) through 2028. The strategy focuses on secure data sharing, harmonised standards, and the use of AI to support faster and better regulatory decision-making.

Source: EMA website (News, Leveraging the power of data for public and animal health)

NEWS

• **APRIL 2025**

CTIS designated as a WHO primary registry

The World Health Organization (**WHO**) has designated the Clinical Trials Information System (**CTIS**) as a primary registry. This status enhances the global visibility and transparency of clinical trials conducted in the European Union (**EU**).

Source: EMA website (News, Clinical Trials Information System designated as WHO primary registry)

PUBLICATION

• **MARCH 2025**

New clinical trial map for the EU

EMA launched a new, interactive clinical trial map via the Clinical Trials Information System (**CTIS**) to improve public access to real-time information on ongoing clinical trials in the EU. The map allows users to search for trials by location and topic, which helps both participants and professionals identify relevant studies.

Source: EMA website (News, New clinical trial map launched in the EU)

NEWS

• **JANUARY 2025**

EMA marks 30 years of progress in science and medicines

To celebrate its 30th anniversary, the European Medicines Agency reflected on three decades of regulatory progress, highlighting its evolving role in enabling safe and effective medicines across the EU. The agency reaffirmed its commitment to scientific innovation, patient safety, and cross-border cooperation.

Source: EMA website (News, EMA celebrates 30 years of progress)

PUBLICATION

• **JANUARY 2025**

EMA's guideline on investigational ATMPs in clinical trials

EMA adopted a new guideline detailing the quality, non-clinical, and clinical requirements for investigational advanced therapy medicinal products (**ATMPs**) in clinical trials.

Source: EMA website (Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials – Scientific guideline)

INTERNATIONAL PUBLICATIONS

Council for International Organizations of Medical Sciences (CIOMS)

PUBLICATION

• **JUNE 2025**

CIOMS's updated Glossary of ICH Terms and Definitions

CIOMS released version 8 of its Glossary of ICH Terms and Definitions, which is a compilation of key terminology from guidelines issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**). The glossary supports a harmonised interpretation of regulatory language and facilitates a global understanding of ICH concepts.

Source: CIOMS website (Publications) (glossary doi: 10.56759/eftb6868)

PUBLICATION

• **JUNE 2025**

New report on benefit-risk balance for medicinal products

A new report from the CIOMS Working Group XII provides insights into evaluating the benefit-risk (**BR**) balance of medicinal products. It details methodologies for establishing BR profiles prior to marketing and emphasises the importance of doing post-marketing reassessments as new data emerge.

Source: CIOMS website (Publications) (report doi: 10.56759/gwfz1791)

• **APRIL 2025**

Chan A-W et al. (2025) SPIRIT 2025 statement: Updated guideline for protocols of randomised trials. BMJ 389:e081477.

doi: 10.1136/bmj-2024-081477

Hopewell S (2025) CONSORT 2025 statement: Updated guideline for reporting randomised trials. BMJ 389:e081123.

doi: 10.1136/bmj-2024-081123

Two widely adopted guidelines on trial protocols and reporting have been updated: Standard Protocol Items: Recommendations for Interventional Trials (**SPIRIT**) and Consolidated Standards of Reporting Trials (**CONSORT**). SPIRIT 2025 and CONSORT 2025 reflect methodological and regulatory developments that have occurred since the previous versions were published (2012 and 2010 respectively). Both updates were published in leading medical journals, including the *BMJ*, and are aimed at enhancing completeness, consistency, and clarity in trial design and reporting.

• **MARCH 2025**

Hennessy S et al. (2025) Real-world data and real-world evidence in regulatory decision-making: Report summary from the Council for International Organizations of Medical Sciences (CIOMS) Working Group XIII. Pharmacoepidemiology and Drug Safety 34(3):e70117.

doi: 10.1002/pds.70117

CIOMS Working Group XIII published a summary of the role of real-world data (**RWD**) and real-world evidence (**RWE**) in regulatory processes. The report outlines challenges related to the use of RWE, methods for evaluating data reliability, and the need for global harmonisation in order to strengthen evidence-based regulation.

ABBREVIATIONS

ACT EU	Accelerating Clinical Trials in the European Union
AI	artificial intelligence
ATMP	advanced therapy medicinal product
BASEC	Business Administration System for Ethics Committees
BR	benefit-risk
CDMS	clinical data management system
CHUV	Lausanne University Hospital
CIOMS	Council for International Organizations of Medical Sciences
ClinO	Clinical Trials Ordinance
CONSORT	Consolidated Standards of Reporting Trials
CRC	Clinical Research Centre
CTIS	Clinical Trials Information System
CtQ	critical to quality
CTU	clinical trial unit
DCT	decentralised clinical trial
eCRF	electronic case report form
ECRIN	European Clinical Research Infrastructure Network
EDC	electronic data capture
EMA	European Medicines Agency
EU	European Union
FADP	Federal Act on Data Protection
FBM	Faculty of Biology and Medicine
FIH	first-in-human
FOPH	Federal Office of Public Health
GCP	good clinical practice
GDPR	General Data Protection Regulation (EU)
HMA	Heads of Medicines Agencies
HRA	Human Research Act
HRO	Human Research Ordinance
HumRes	Human Research Switzerland
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICH GCP	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice
IP	investigational product
ISF	investigator site file
QbD	quality by design
RWD	real-world data
RWE	real-world evidence
SCTO	Swiss Clinical Trial Organisation
SNCTP	Swiss National Clinical Trials Portal
SOP	standard operating procedure
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
TMF	trial master file
UNIL	University of Lausanne
WHO	World Health Organization
WMA	World Medical Association

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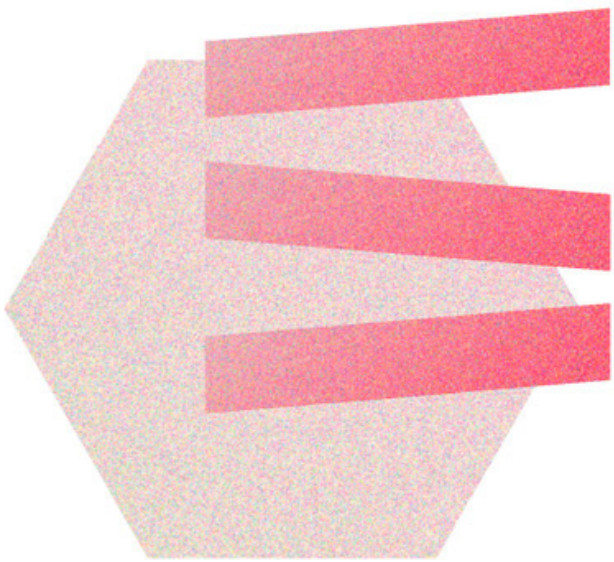
Sources of information

- 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; at Swiss academic organisations and health associations; and professional associations.
- Additionally, we review major clinical research journals.



Regulatory Affairs Platform

The Regulatory Affairs Platform is one of the Swiss Clinical Trial Organisation's (**SCTO's**) eight topic-based 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 Platforms' Tools & Resources website.

Contact information

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