What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH | June 2025 | **Newsletter** | **# 50**

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New President and Vice-president elected

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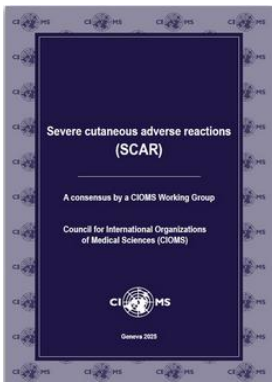
Top ten CIOMS publications

Just published

Severe cutaneous adverse reactions

A consensus by a CIOMS Working Group



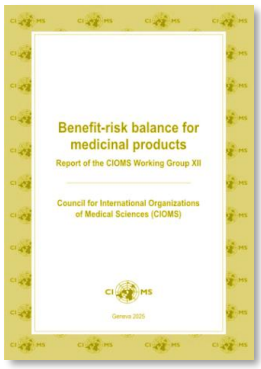
Cutaneous ADRs (cADRs) affect only 2–3% of all hospitalized patients, but have a wide spectrum of clinical manifestations, are caused by various medicinal products, and result from different pathophysiologic mechanisms. Their diagnosis and management are therefore challenging.

The aim of the CIOMS Working Group for severe cutaneous adverse reactions (SCAR) was to contribute to a balanced, global perspective to SCAR detection, susceptibility factors, severity, outcome and probability through causality assessment tools, monitoring and risk management during medicinal product development and post-authorization phases. The Group has just published its report, to serve as a global reference for those involved in product life cycle management or clinical practice.

☞ **Download the report (https://doi.org/10.56759/lrty1600) here**

Benefit-risk balance for medicinal products

Report of the CIOMS Working Group XII



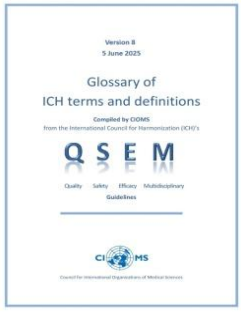
In recent years, the practice of benefit–risk assessment (BRA) has adopted more systematic and transparent methods. However, the increasing complexity of pharmaceuticals now demands greater rigour and more comprehensive evaluation for establishing the safety and efficacy of a product or its benefit-risk balance. Moreover, many advances and changes have emerged since the 1998 CIOMS report on this topic, which had long remained the single authoritative publication in the field of benefit–risk balance. CIOMS therefore brought together a Working Group to review the BR landscape, provide guidance, best practices and case studies on when and how to conduct BRA of a medicinal product, including for special situations where the magnitude of benefits and risks remains uncertain, and for emergencies.

As well as promoting adoption of a lifecycle approach to BRA, this new report also emphasizes a pragmatic, patient-centric approach, so that the benefits and harms of a medicine, as experienced by the patients using them, are fully understood and evaluated.

☞ **Download the report (https://doi.org/10.56759/gwfz1791) here**

CIOMS Glossary of ICH terms and definitions

Version 8



An updated version of the CIOMS Glossary of ICH terms and definitions is now available on the CIOMS website. Version 8 has been updated with definitions from eight different ICH guidelines that have been published in recent months.

The CIOMS ICH Glossary combines the definitions from across the current, publicly available guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

☞ **Access CIOMS Glossary version 8 (https://doi.org/10.56759/eftb6868) on the CIOMS webpage or via the ICH webpage.**

Better engagement, better evidence: working in partnership for clinical trials

CIOMS' Secretary-General, Dr Lembit Rägo, is a co-author of a recently published article in *The Lancet* which provides an overview of the domain of clinical trials. It also defines key actions for stakeholders across the clinical trial ecosystem for systematic engagement of patient, public, and community stakeholders. As the article notes, recognition is increasing that many stakeholders need to participate in trial planning, governance, and implementation activities if engagement is to strengthen scientific and ethics outcomes. It notes the multitude of guidance documents, frameworks, and implementation toolkits are available to steer practice at global, national, and local levels. These include four of CIOMS' publications: *International ethical guidelines for health-related research involving humans*, *Patient involvement in the development, regulation and safe use of medicines*, *Clinical research in resource-limited settings* and *International guidelines on good governance practice for research institutions Ditto*.

The authors comment, however, that although important advances have been made in integrating engagement into standard clinical trial practice, many challenges remain, including systemic gaps, limited engagement beyond tokenistic involvement, and structural inequities. They call for action across the clinical trial ecosystem, including strengthening policies, enhancing funding mechanisms, improving regulatory oversight, advocacy, and education of all stakeholders about engagement.

☞ **Better engagement, better evidence: working in partnership with patients, the public, and communities in clinical trials with involvement and good participatory practice - ScienceDirect**

CIOMS Working Group news

CIOMS Working Groups (WGs) are at the core of the CIOMS's activities. Composed of experts from academia, the pharmaceutical industry, regulatory agencies and international organizations, they develop consensus recommendations on specific topics. Four WGs are currently in operation, as shown below. WG XIV held meetings in April and June 2025, while WG XVI held its second meeting in June 2025. Two WGs — on severe cutaneous adverse reactions and benefit–risk balance for medicinal products — finalized their reports earlier this year.

☞ **Working Group XVI: Development safety update report**

☞ **Working Group XIV: Artificial Intelligence in Pharmacovigilance**

☞ **Working Group on Educational standards for health professionals participating in medicines development**

☞ **Working Group XV: Pharmacoepidemiology for public health**

☞ **All WG concept notes and meetings are available on the CIOMS webpages**

CIOMS@ International events

ICPM 2025

9–11 April 2025, Amsterdam, The Netherlands

The 21st International Conference on Pharmaceutical Medicine, hosted by the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and the Dutch Association for Pharmaceutical Medicine, featured a broad spectrum of critical topics. CIOMS' Secretary-General, Dr Lembit Rägo, spoke on medical product development and the need for it to be both data centric and patient centric. He underscored that while those working in the pharmaceutical industry or involved in clinical trials are informed about product development, those involved in patient care and not (directly) involved in product development are likely not to be. Yet with increasing use of real-world data, more health professionals will become involved in product development given that they produce and document data in health care delivery. Indeed, they can play a pivotal role in health product development by helping to ensure that products are clinically relevant, safe, effective and user-friendly.

Above from left: Dr Lembit Rägo (CIOMS), Prof Kotone Matsuyama, Dr Eric Klaver (President of IFAPP), Dr Varvara Baroutsou (immediate past President of IFAPP). Dr Lujain Al-Qodmani (Past President of World Medical Association), Prof Chieko Kurihara and Prof Sandor Kerpel-Fronius.

ICH Assembly Meeting

13–14 May 2025, Madrid, Spain

The Assembly of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met in-person in May 2025, in Madrid, Spain, in parallel with meetings of 11 Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Steering Committee. CIOMS was represented by Secretary-General Dr Lembit Rägo.

ICH welcomed: DINAVISA (Dirección Nacional de Vigilancia Sanitaria), Paraguay; the Ministry of Health of Kuwait; and Superintendencia de Regulación Sanitaria), El Salvador as new ICH Observers, bringing the total number of Members and Observers to 23 and 41 respectively.

The Assembly adopted four new topics for harmonization:

- Considerations for the use of real-world evidence (RWE) to inform regulatory decision making with a focus on effectiveness of medicines — a new ICH Efficacy Guideline that will propose a systematic approach to using RWE in regulatory decision making.
- Framework for determining the utility of comparative efficacy studies in biosimilar development programs — a new ICH Multi-disciplinary Guideline to address factors to consider in deciding the utility of comparative efficacy studies in biosimilar development programmes.
- Natural history studies and registry data to advance rare disease drug development – a new ICH Efficacy Guideline to provide high-level, harmonized principles for designing and conducting natural history studies and registries for rare diseases.
- Comparability of advanced therapy medicinal products (ATMPs) subject to changes in their manufacturing process (Annex to ICH Q5E) – a new Annex to the ICH Multidisciplinary Guideline ICH Q5E, addressing the unique development and regulatory challenges of ATMPs, such as gene and cell therapies.

(**Above**): Delegates at the ICH Assembly Meeting in Madrid, May 2025.

MedDRA

During the ICH Management Committee meeting, NMPA (National Medical Products Administration), China and SFDA (Saudi Food and Drug Authority), Saudi Arabia were appointed as Regulatory Members, and IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) as a Standing Observer, to the MedDRA Steering Committee. MedDRA now has over 9,000 subscribing organizations across 141 countries and is accessible in 24 languages. Collaboration with international organizations is ongoing, with continued efforts to support and develop mappings between MedDRA and other terminologies.

☞ **Further meeting information**

IFMSA Youth Pre-World Health Assembly

17–18 May 2025, Geneva, Switzerland

Every year, the International Federation of Medical Students Associations (IFMSA) hosts a Youth Pre-World Health Assembly (Youth PreWHA), during which it organizes sessions on global health topics and facilitates interactive workshops on important health issues. These aim to help medical students to enhance both their knowledge of global health issues and governance, and their capacity to advocate and participate in the global health arena. The 2025 Youth PreWHA brought together 75 dedicated and talented young advocates.

CIOMS participated in some of the Youth PreWHA events and invited IFMSA representatives to visit the CIOMS Secretariat offices. Commented CIOMS' Secretary-General Dr Lembit Rägo: "The Youth PreWHA offers CIOMS a tremendous opportunity to meet and connect with potential future leaders in health. Our discussions were lively and engaging and benefited from a range of different perspectives."

Above: Representatives of IFMSA and CIOMS Secretary-General Dr Lembit Rägo during the IFMSA visit to CIOMS Secretariat offices.

☞ **Further information: IFMSA**

Save the date: ISOP 24th Annual Meeting, Cairo, Egypt

ISOP – the International Society of Pharmacovigilance – will hold its 24th Annual Meeting in Cairo Egypt, 24–27 October 2025, with the theme of Pharmacovigilance: Back to the Future.

☞ **24th ISoP Annual Meeting**

Regulatory news roundup

CDSCO Central Drugs Standard Control Organization, India

Biosimilar authorization guidelines

CDSCO has released draft revisions to its guidance on biosimilar marketing authorization. The revisions reflect guidance published by the World Health Organization in 2023. Key changes in the draft guidance include the introduction of scientific considerations and key principles for licensing biosimilars. The consultation period for the guidelines is now closed. But the draft guidance remains available.

☞ **Draft guidelines on similar biologics**

EMA European Medicines Agency

Leveraging the power of data

EMA and the Heads of Medicines Agencies (HMA) have published a joint workplan: *Data and AI in medicines regulation to 2028*. It sets out how the European medicines regulatory network plans to use large volumes of regulatory and health data, as well as new tools, to encourage research, innovation, and to support regulatory decision making for better medicines that reach patients more quickly.

The workplan aims to enable efficient discovery, access and use of the network's data assets through cataloguing and strengthening data quality. Key initiatives of the workplan include supporting EMA's scientific committees and the pharmaceutical industry in evaluating AI through the medicines lifecycle, developing guidance on AI in clinical development and in pharmacovigilance, fostering EU-wide and international collaboration, and providing the network with training on AI and a framework for sharing and collaborating on AI tools. The aim is to facilitate safe and responsible use of AI that benefits public and animal health.

☞ **Workplan: Data and AI in medicines regulation 2025–2028**

CTIS now designated a primary registry

The Clinical Trials Information System (CTIS), which supports the running of clinical trials for human medicines in the European Union (EU) and the European Economic Area, has been designated as a primary registry by the World Health Organization within the International Clinical Trials Registry Platform (ICTRP). Becoming a primary registry signifies that CTIS adheres to specific criteria for content, data quality and validity, accessibility, unique identification, technical ability, and administration. This ensures comprehensive research information is accessible to healthcare decision makers globally.

CTIS includes a public searchable database for healthcare professionals, patients and citizens to deliver the elevated level of transparency foreseen by the EU Clinical Trials Regulation. CTIS also includes a trial map that makes it easier for patients and healthcare professionals to find recruiting clinical trials near them.

☞ **Further information: Clinical Trials Information System (CTIS) | Searchable trial database | Clinical Trial Map**

Streamlining for biosimilars

EMA is exploring improvements to the development and evaluation of biosimilar medicines, while upholding strict EU safety standards. It anticipates that this approach will improve access to biosimilars for patients in the EU and ensure that Europe is an attractive market in which to develop these treatments. The approach – outlined in a draft reflection paper – could potentially reduce the amount of clinical data needed for the development and approval of biosimilar medicines. Stakeholders can send their comments on the reflection paper via an online EUSurvey until 30 September 2025.

☞ **Reflection paper on a tailored clinical approach in biosimilar development**

☞ **Submission of comments via EUSurvey**

1st AI tool to diagnose inflammatory liver disease in biopsy samples qualified

EMA's human medicines committee (CHIMP) has issued the first Qualification Opinion on an innovative development methodology based on artificial intelligence (AI). The tool, called AIM-NASH, helps pathologists analyse liver biopsy scans to identify the severity of MASH (metabolic dysfunction associated steatohepatitis; formerly

known as non-alcoholic steatohepatitis NASH) in clinical trials. MASH is linked to obesity, type 2 diabetes, high blood pressure, abnormal cholesterol, and belly fat. If untreated, it can lead to advanced liver disease. The AIM-NASH tool is expected to enhance the reliability and efficiency of clinical trials for new MASH treatments by reducing variability in measuring disease activity (inflammation and fibrosis).

☞ **Qualification opinion**

☞ **Of related interest: NAMS for preclinical safety and efficacy testing workshops in Australia**

ICH International Council for Harmonization

Viral safety evaluation training modules

Training materials for the ICH Q5A(R2) *Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin guideline* are now available. Modules 0–3 are designed for industry and regulatory audiences and aimed at clarifying and illustrating key concepts specific to viral safety that were updated in the ICH Q5A(R2) guideline revision (which was adopted in November 2023). They also support implementation of the guideline, using examples for illustrative purposes.

☞ **Training modules**

Guideline on stability testing

The ICH Q1 draft guideline on *Stability testing of drug substances and drug products* has reached Step 2b of the ICH Process and is available for public consultation until 15 July 2025. Combining and modernizing the content of ICH Q1A-F series and ICH Q5C, the final and comprehensive stability guideline will address a range of product types.

☞ **ICH Q1 Draft Guideline**

☞ **Stakeholders can provide comments by e-mailing the ICH Secretariat: at step2comments@ich.org, using the ICH Template in Excel format.**

Guideline on inclusion of pregnant and breastfeeding Individuals in clinical trials

This E21 guideline aims to serve as a globally accepted framework and best practices for facilitating inclusion and/or retention of pregnant and breast-feeding individuals in clinical trials. Covering principles and practices to enable the collection of a sufficiently robust set of safety, efficacy, and/or pharmacokinetic data in pregnant and breast-feeding individuals, the guideline will better inform clinical decision making in medicinal product use (for improved product labelling, for example). Most importantly, it will establish a common understanding between regulatory authorities, industry and other stakeholders and harmonize strategies and methodologies for enrolment and retention of pregnant and/or breast-feeding individuals for clinical trials, and overall drug development plans. The guideline has now been endorsed for public consultation.

☞ **Further information is available here**

MHRA Medicines & Healthcare products Regulatory Agency

Draft guideline on use of real-world data

This guideline will provide clinical trial sponsors with points to consider and key principles that should be considered when planning a clinical trial that will include a real-world data (RWD) external control arm (ECA) and that will require regulatory approval. The guideline is specifically aimed at sponsors planning to use RWD ECAs, but many of its general principles will be relevant for external controls drawn from other sources, such as previously completed clinical trials. Points covered include the circumstances under which the use of RWD ECAs might be most appropriate, and clinical trial design and analysis considerations with an emphasis on minimizing bias.

☞ **The draft guideline is available here**

NMPA National Medical Products Administration, China

Chinese Pharmacopoeia 2025 edition

Officially released on 25 March by the National Medical Products Administration (NMPA) and National Health Commission, the Chinese Pharmacopoeia 2025 edition will replace the previous 2020 edition as of 1 October 2025. Implementation of the new pharmacopoeia is intended to enhance standards and drive an overall improvement in industry quality levels in China's pharmaceutical market.

The updated Pharmacopoeia introduces major changes to the standards system, testing methods, traditional Chinese medicine quality control, and biological products regulation, including the adoption of the ICH Q4B international harmonization standard. These changes will significantly

impact marketing authorization holders, manufacturers, and overseas companies entering or operating in the Chinese market.

NMPA has issued clarifications of the transition requirements.

☞ **NMPA announcements (Chinese language only)**

PMDA Pharmaceuticals and Medical Devices Agency, Japan

Promoting paediatric drug development

PMDA has published details of the steps it is taking to promote the development of drugs for use in children in Japan. PDMA's report (published in Japanese translated into English) outlines the need for action. The agency notes growing concerns about growing 'drug loss' in Japan, whereby pharmaceuticals approved in the European Union and the US are not being developed for Japanese patients. The problem is particularly challenging for paediatric and orphan drugs.

During clinical trial consultations for adult drug development PMDA will therefore actively verify the status of paediatric drug development and provide advice or guidance to ensure that paediatric drug development does not lag behind adult drug development. Companies seeking authorization for new drugs or indications may be obligated to plan paediatric development.

☞ **Further information**

U.S. FDA U.S. Food and Drug Administration

Replacing animal testing

FDA is planning to replace animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods. The new approach is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering R&D costs, and ultimately, drug prices.

The FDA's animal testing requirement will be reduced, refined, or potentially replaced using a range of approaches, including AI-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies or NAMs data). Implementation of the regimen will begin at once for investigational new drug applications, where inclusion of NAMs data is encouraged, and outlined in a roadmap. The agency will also begin using pre-existing, real-world safety data from other countries that have comparable regulatory standards and where the drug has already been studied in humans, for deciding efficacy.

FDA and federal partners will host a public workshop later this year to discuss the roadmap and gather stakeholder input on its implementation. Over the coming year, FDA aims to launch a pilot program allowing select monoclonal antibody developers to use a primarily non-animal-based testing strategy, under close FDA consultation. Findings from an accompanying pilot study will inform broader policy changes and guidance updates expected to be rolled out in phases.

☞ **FDA roadmap for reducing pre-clinical testing**

☞ **Of related interest: EU Innovation Network Scanning Report: New Approach Methodologies**

☞ **Of related interest: European Commission roadmap towards phasing out animal testing**

Other news

CIRS Centre for Innovation in Regulatory Science

Enhancing international collaboration

CIRS R&D Briefing 97 focuses on the Access Consortium and Project Orbis. The Consortium is a coalition of regulatory authorities working together to promote greater regulatory collaboration and alignment of regulatory requirements, while Orbis was started by the U.S. FDA Oncology Center of Excellence to provide a framework for concurrent submission and review of oncology products among international partners. Both frameworks are designed to speed up patient access to innovative medicines through the leveraging of shared regulatory activities across different jurisdictions.

Assessment of their impact on regulatory processes and timelines has shown that the Access Consortium and Project Orbis have both reduced submission gaps and approval times for new active substances, while expanding their therapeutic reach among participating regulatory agencies.

☞ **CIRS R&D Briefing 97: Access Consortium and Project Orbis New Active Substance Approvals across Eight National Regulatory Authorities: A five-year comparative study**

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CIOMS Secretariat news

Newly elected CIOMS President and Vice-president

A new CIOMS president and vice-president were elected at the virtual CIOMS 2025 General Assembly on 10 June 2025. Professor Stella Blackburn, representing the International Society for Pharmacoepidemiology (ISPE), was elected as President, and Professor Dominique Sprumont, representing the World Medical Association, was elected as Vice President.

Outgoing president Dr Hervé Le Louët and vice-president Dr Samia Hurst were warmly thanked by Dr Lembit Rägo for their contributions, which have had a lasting and significant impact on the work of CIOMS. Dr Le Louet and Dr Hurst will both continue to serve on the CIOMS Executive Committee, whose current members were confirmed in a virtual meeting in April 2025.

CIOMS' Secretary-General Dr Rägo gave an overview of the achievements of 2024, but concluded by noting that a rapidly changing world, CIOMS must adapt, drawing on its 75 years of experience to remain effective and relevant in the future.

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[a] Also available in Chinese [b] Also available in: Arabic, Chinese, French, Japanese, Korean, Polish, Portuguese, Russian, Spanish, Ukrainian [c] Also available in Chinese

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