What's on @ CIOMS
COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES
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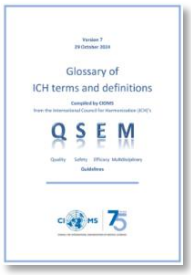
In this newsletter

CIOMS news

Just published



Glossary of ICH terms and definitions: Version 7

This 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). It is periodically updated, and is introduced on the ICH website **here**.

The glossary can be freely downloaded in PDF format **here**. In addition, it is being shared with ICH members and observers in a database-compatible format.

Rapid response

Rägo L, Sawyer J. **Keeping ethical pace with medical research: the 10th revision of the Declaration of Helsinki**. 19 November 2024. Rapid response to: Sheather J. Declaration of Helsinki puts global justice up front. BMJ. 2024 Nov 1;387:q2405.

☞ Read more about the revised Declaration of Helsinki on page 5.

Webinar

Real-world data and real-world evidence in regulatory decision making

3 December 2024 (virtual platform) – Repeat planned for 23 January 2025*

Experts from the CIOMS Working Group XIII introduced the main concepts of their recently published consensus report on *Real-world data and real-world evidence in regulatory decision making*. Such decisions include, for example, whether or not to make a product available for use (authorisation), to cover the costs of its use (reimbursement), or to use a product for a particular patient group (clinical use). ☞ **https://cioms.ch/webinars**

*Registration for the repeat webinar will open in early January. The recording will be made available after the repeat webinar.

(**Above**) The webinar speakers and panellists. An additional panellist will join in January.

CIOMS Working Groups

Meetings held (fourth quarter of 2024):

Recommended standards for education and training

9th Meeting, 29–30 October 2024, Geneva (Switzerland)

☞ **Working Group webpage**

Pharmacoepidemiology for public health

4th Meeting, 21 October 2024 (virtual)
5th Meeting, 4–5 December 2024, Geneva

☞ **Working Group webpage**

Ongoing Working Groups (WG):

- ☞ Pharmacoepidemiology for public health (WG XV)
- ☞ Artificial Intelligence in Pharmacovigilance (WG XIV)
- ☞ Recommended standards of education and training for health professionals participating in medicines development
- ☞ Severe Cutaneous Adverse Reactions to Drugs (SCAR)
- ☞ Benefit-Risk Balance for Medicinal Products (WG XII)

Concept papers and meeting minutes are published on the Working Groups' webpages.

CIOMS@ International events

International Society of Pharmacovigilance (ISoP)

23rd Annual Meeting, 1–5 October 2024, Montreal (Canada)

(**Above**) Speakers at the session on CIOMS Guidelines. From left: Taxiarchis Botsis, Niklas Norén (both from CIOMS Working Group XIV), Ana Claudia Ianos (CIOMS Working Group XII) and Manal Younus (CIOMS Executive Committee).

ISoP is a CIOMS member, and the two organizations share a common goal of advancing pharmacovigilance. The 2024 annual ISoP meeting included a dedicated session with updates from three CIOMS Working Groups (WG): Benefit-Risk Balance for Medicinal Products (WG XII, ongoing), Real-world data and real-world evidence in regulatory decision making (WG XIII, completed) and Artificial intelligence in pharmacovigilance (WG XIV, ongoing). The session received very positive feedback.

☞ **https://isop2024montreal.org/**

☞ Abstract book: Drug Safety, 2024, 17 Sep. (not open-access)

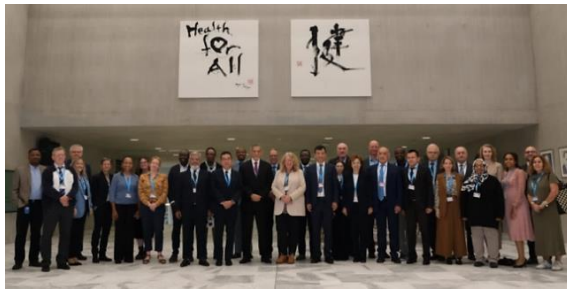
WHO Expert Committee on Specifications for Pharmaceutical Preparations

58th meeting, 7–11 October 2024, Geneva (Switzerland)

CIOMS Secretary-General Lembit Rägo participated as a temporary advisor in the meeting of this WHO Committee, which oversees the maintenance of *The International Pharmacopoeia* and provides guidance for use by WHO and regulatory authorities in WHO Member States to ensure that medicines meet unified standards of quality, safety and efficacy. It also recommends regulatory guidelines of importance to multisource medicines used globally.

☞ **WHO Expert Committee webpage**

☞ WHO. **Guidelines: Norms and standards for pharmaceuticals**



(**Above**) The meeting participants at WHO Headquarters.

International Conference of Drug Regulatory Authorities ICDRA) 2024

14–18 October 2024, New Delhi (India)

(**Above**, **from left**) The workshop speakers and panellists: Heran Gerba (Ethiopian Food and Drug Authority), Vasee Moorthy (WHO), Lembit Rägo (CIOMS), Samvel Azatyan (WHO), Olga Rassokhina (Paul-Ehrlich-Institut, Germany) and Peter Twomey (EMA; Regulatory Chair of the ICH E6(R3) Expert Working Group on Good Clinical Practice).

☞ **ICDRA 2024: Programme**

The 19th ICDRA was hosted by the Central Drugs Standard Control Organization (CDSCO) of India. CIOMS Secretary-General Lembit Rägo chaired the workshop titled "**Clinical trials: from WHA Recommendations to Action**", and also briefly introduced the recent revision of the Declaration of Helsinki (see page 5) and the CIOMS 2016 ethical guidelines. The new WHO Guidance for best practices for clinical trials incorporates elements from several CIOMS Working Group reports.

(**Below**) The CIOMS Secretary-General also participated in the **WHO Pharmacovigilance Partners' Meeting,** which was held on the margins of ICDRA 2024 to discuss a Global Smart Pharmacovigilance Strategy.

Images courtesy of conference organizers

CIOMS @ International events (continued)

ICH Assembly meeting

5–6 November 2024, Montreal (Canada)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) continues to expand. Three new observer organisations were welcomed at the Assembly meeting, bringing ICH to a total of 23 members and 38 observers. The Assembly was updated on progress on ICH guideline development, implementation, and other topics. The next ICH Assembly meeting is planned on 13 and 14 May 2025 in Madrid, Spain.

☞ **ICH Press release, 13 November 2024**

(**Above**) Participants at the ICH Assembly meeting. CIOMS is an ICH observer and was represented by its Secretary-General, Lembit Rägo. CIOMS has been collaborating with ICH on specific topics since the early 2000s. To support ICH terminology harmonization, a new file-sharing agreement for the CIOMS glossary of ICH terms and definitions (see page 2) was approved at the Montreal meeting.

American Statistical Association (ASA) Safety Working Group

Quarterly scientific webinar, 6 November 2024 (virtual event)

This webinar was held to discuss new recommendations on grouping MedDRA preferred terms to support signal detection and evaluation, as well as description of a product's safety profile through labelling. One of the conclusions was that the CIOMS recommendations on MedDRA Labeling Groupings (MLG) should be considered when finalizing groupings of adverse reaction terms in the proposed labelling at the product submission stage.

(**Above**) Scott Proestel and Radhika Rao presented the consensus recommendations from the CIOMS Working Group report on MedDRA Labeling Grouping (MLG), which proposes a standardized approach to grouping adverse reactions in product safety labels.

WHO Technical Advisory Group on WHO-Listed Authorities (TAG-WLA)

18 November 2024, Geneva (Switzerland)

This group provides technical advice on designating and publicly listing regulatory authorities as operating at a globally recognized advanced level of performance, replacing the procurement-oriented concept of "stringent regulatory authorities". The CIOMS Secretary-General, Lembit Rägo is a TAG-WLA member and participated in the meeting.

☞ **More information on the WHO Listed Authorities (WLA) framework**

European Pharmacovigilance Congress 2024

18–19 November 2024, online; 22 November 2024, Milan (Italy)

☞ **Congress webpage**

This annual conference is a major event for professionals and decision makers in the field of pharmacovigilance. Session 10 on real-world data and real-world evidence was held in a virtual format and chaired by the CIOMS Secretary-General, Lembit Rägo. He introduced the recently published CIOMS Working Group XIII report on Real-world data and real-world evidence in regulatory decision making, which is appreciated for the pragmatic, globally applicable guidance it provides on this topic.

CIOMS @ International events (continued)

WHO Paediatric Regulatory Network (PRN)

18–19 November 2024, Istanbul (Türkiye)

The PRN is a global network that supports the availability of quality-assured medical products for children. CIOMS provided an update on two recent developments that are particularly relevant to the regulation of paediatric products: the World Medical Association's revised Declaration of Helsinki (see more below), which includes provisions for protecting children in research, and the new CIOMS guidelines on Real-world data and real-world evidence in regulatory decision making.

☞ **More about the WHO PRN**

(**Above**) CIOMS Secretary-General Lembit Rägo, during his presentation

Third Boao International Conference on Real-world Studies of Medical Products

22–24 November 2024; Boao, Hainan Province (China)

The CIOMS Working Group XIII report on Real-world data and real-world evidence in regulatory decision making was the topic of a keynote address at the third annual Boao International Conference.

Launched in June 2019, the Boao Lecheng pilot project serves to test and develop the approach used by China's National Medical Products Administration (NMPA) for considering real-world data in regulatory decision-making on medical products.

(**Above**) Lembit Rägo (CIOMS) gave a keynote speech by remote participation.

☞ See also: Li P, Wang S, Chen Y. **Use of Real-World Evidence for Drug Regulatory Decisions in China: Current Status and Future Directions**. Ther Innov Regul Sci. 2023 Nov;57(6):1167-1179.

WMA — World Medical Association

Revised Declaration of Helsinki

Adopted at the 75th WMA General Assembly, 19 October 2024, Helsinki (Finland)

The World Medical Association (WMA) has adopted a new Revision of its Declaration of Helsinki (DoH), the global reference for medical research involving human participants. CIOMS Executive Committee members Johannes JM van Delden, Dominique Sprumont and Samia Hurst actively contributed to the revision process, and Dominique Sprumont represented CIOMS in this historic meeting.

The amended DoH responds to new challenges in research ethics. It calls for a fair distribution of the benefits, risks and burdens of research; respect for and meaningful engagement of research participants and their communities; addressing the health needs of those in situations of vulnerability by including them in research with due protection; scientific integrity; and a scientifically sound and rigorous design and execution of research.

Image from WMA's post on the "X" platform, 25 October 2024

The 2024 revision of the Declaration of Helsinki (DoH) is the product of a long consultative process, in which CIOMS was represented. **The 2024 DoH has moved closer to the principles embedded in CIOMS guidance.(1–3)**

☞ **WMA Press release**, 21 October 2024 | **WMA. Declaration of Helsinki**

☞ **JAMA, Online First, 19 October 2024** (includes the revised DoH, a number of related articles, and a **podcast**).

☞ Related CIOMS guidance: **(1)** **International ethical guidelines for health research involving humans**. 2016.
(2) **Clinical research in resource-limited settings**. 2021.
(3) **International guidelines on good governance practice for research institutions**. 2023.

News roundup

Regulatory guidance

EMA European Medicines Agency

Reflection paper on the use of artificial intelligence in the product lifecycle

The EMA has finalized its reflection paper on using artificial intelligence and machine learning at all steps of a medicine's lifecycle. The draft document was released for comments in July 2023 (see the CIOMS September 2023 newsletter). More than 1300 comments were received and addressed.

☞ **EMA. The use of Artificial Intelligence (AI) in the medicinal product lifecycle** (webpage). Reflection paper, **9 September 2024**

Reflection paper on single-arm clinical trials

This reflection paper focuses on single-arm trials (SATs) submitted as pivotal evidence for establishing the efficacy of medicinal products. Many of the considerations also apply to the assessment of safety, and many translate to other SATs, e.g. those used for decision making in early product development.

☞ **EMA. Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation application. 9 September 2024**

Using clinical trial data in medicines evaluation

An interim report on a proof-of-concept pilot has found that submission of actual clinical study data in electronic structured format (rather than as summaries or PDF listings) can speed up the evaluation process. The pilot was launched in July 2022 and will be extended until further notice based on these findings.

☞ **EMA. Use of clinical study data in medicine evaluation** (webpage) Interim report, **18 October 2024**

FDA U.S. Food and Drug Administration

Best practices for safety surveillance

This FDA best-practice document sets forth risk-based principles for ongoing postmarketing safety surveillance. It adopts a multidisciplinary, lifecycle approach, giving pragmatic advice on how to identify and evaluate safety signals, and how to mitigate any identified risks. The document is useful reading for anyone wishing to understand more about safety surveillance of medicines.

☞ **FDA. Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products. January 2024.**

Diversity in clinical studies

This updated draft guidance relates to the format and content of Diversity Action Plans to increase enrollment of participants from historically under-represented populations in clinical studies, in order to generate stronger and more generalizable evidence for the intended use population.

☞ **FDA. Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies. June 2024.**

Questions and Answers on use of electronic systems in clinical investigations

This Guidance for Industry provides the FDA's recommendations on what is needed for electronic systems, electronic records and electronic signatures to be considered trustworthy, reliable, and generally equivalent to paper records.

☞ **FDA. Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations. Questions and Answers. October 2024.**

Emergency response strategies

ICMRA International Coalition of Medicines Regulatory Authorities

Facilitating platform clinical trials

Platform trials, which evaluate multiple inter–ventions within a shared framework, could provide actionable results in emergencies. A recent ICMRA paper discusses opportunities and challenges.

☞ **Facilitating Platform Clinical Trials During Global Public Health Emergencies. 19 November 2024.**

Preserving the effectiveness of antimicrobials

In this statement, ICMRA members reiterate that tackling antimicrobial resistance is a top priority, and commit to playing their part in doing so.

☞ **Global regulators commit to playing their part in tackling antimicrobial resistance as a priority. 21 November 2024.**

CIOMS cited

Scientific journals

Fretheim A, Elstrøm P, Julin CH, et al. **Why were so few randomized trials of public health and social measures conducted during the COVID-19 pandemic?** The Norwegian experience. Trials. 2024 Oct 12;25(1):673. doi: 10.1186/s13063-024-08547-2

Jobson E, Garcia M, Sharek D, et al. **Embedding patient engagement in the R&D process of a life sciences company through co-creation with a patient expert R&D board: a case study**. Res Involv Engagem. 2024 Nov 6;10(1):116. doi: 10.1186/s40900-024-00631-w

Nix HP, Weijer C, Taljaard M. **Are pragmatism and ethical protections in clinical trials a zero-sum game?** Clin Trials. 2024 Oct 15:17407745241284798. doi: 10.1177/17407745241284798

Schönweitz FB, Ruess AK, McLennan S, et al. **Where is the exit? The ethical importance of exit plans in clinical trials with neural implants**. Brain Stimul. 2024 Sep-Oct;17(5):1145-1154. doi: 10.1016/j.brs.2024.09.010

Stagi L, Bocchi I, Bernardini D, et al. **The evolution of the Pharmacovigilance department in the pharmaceutical industry: results of an Italian national survey**. Ther Adv Drug Saf. 2024 Nov 4;15:20420986241293296. doi: 10.1177/20420986241293296

Whelan AM. **Dobbs and the Destabilization of Clinical Trials**. Vanderbilt Law Review. 2024: 77; 1381-1467. (Abstract; Download)

JAMA, 19 October 2024 (online first, to coincide with publication of the revised Declaration of Helsinki)

Bloom L. **Revisiting the Declaration of Helsinki-A Patient-Centered Perspective**. JAMA. 2024 Oct 19. doi: 10.1001/jama.2024.22077.

Reis AA, Upshur R, Moodley K. **Future-Proofing Research Ethics-Key Revisions of the Declaration of Helsinki 2024**. JAMA. 2024 Oct 19. doi: 10.1001/jama.2024.22254

Resneck JS Jr. **Revisions to the Declaration of Helsinki on Its 60th Anniversary: A Modernized Set of Ethical Principles to Promote and Ensure Respect for Participants in a Rapidly Innovating Medical Research Ecosystem**. JAMA. 2024 Oct 19. doi: 10.1001/jama.2024.21902

Saenz C, Carracedo S. **The Revision of the Declaration of Helsinki Viewed From the Americas-Paving the Way to Better Research**. JAMA. 2024 Oct 19. doi: 10.1001/jama.2024.22270

Consensus Study Report

National Academies of Sciences, Engineering, and Medicine (NASEM). 2024. **Advancing Clinical Research with Pregnant and Lactating Populations: Overcoming Real and Perceived Liability Risks**. Washington, DC: The National Academies Press. doi: 10.17226/27595

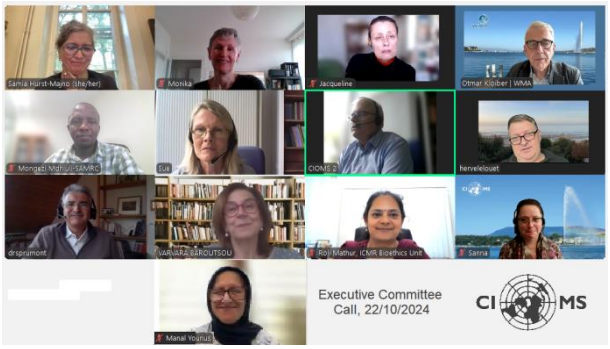
Dashboard

Duke-Margolis Institute for Health Policy. **International Harmonization of Real World Evidence Standards Dashboard**.

CIOMS Secretariat news

CIOMS Executive Committee

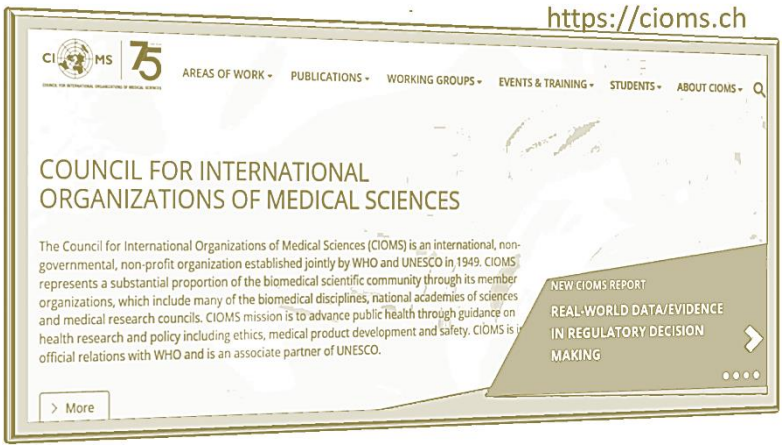
22 October 2024 (virtual meeting)



The CIOMS Executive Committee members discussed the role of CIOMS in recent developments, including the work with WHO to promote best practices for clinical trials (see page 3) and the revision of the WMA's Declaration of Helsinki (see page 5). They also reviewed the procedures for the upcoming elections of the CIOMS President, Vice President and Board members at the CIOMS 2025 General Assembly.

☞ **More about CIOMS governance**

Find us on the web



1 October – 15 December 2024

25 414 visitors from

171 countries

24 737 subscribers

Top ten downloaded CIOMS publications

1 October– 15 December 2024

2024	Glossary of ICH terms and definitions (Versions 6 and 7)	1294
2024	Real-world data and real-world evidence in regulatory decision making [a]	341
2024	CIOMS Cumulative glossary, with a focus on pharmacovigilance (Annivers. Edition)	287
2016	International ethical guidelines for health-related research involving humans [b]	215
2024	Introduction to MedDRA Labeling Grouping (MLG)	160
2005	Management of safety information from clinical trials [c]	122
2023	International guidelines on good governance practice for research institutions	110
2010	Practical Aspects of Signal Detection in Pharmacovigilance [d]	94
2020	Drug-induced liver injury (DILI)	88
2022	Patient involvement in the development, regulation and safe use of medicines [e]	85

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

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The CIOMS team wishes you every success in 2025!