What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

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WWW.CIOMS.CH June 2024 | **Newsletter** **# 46**

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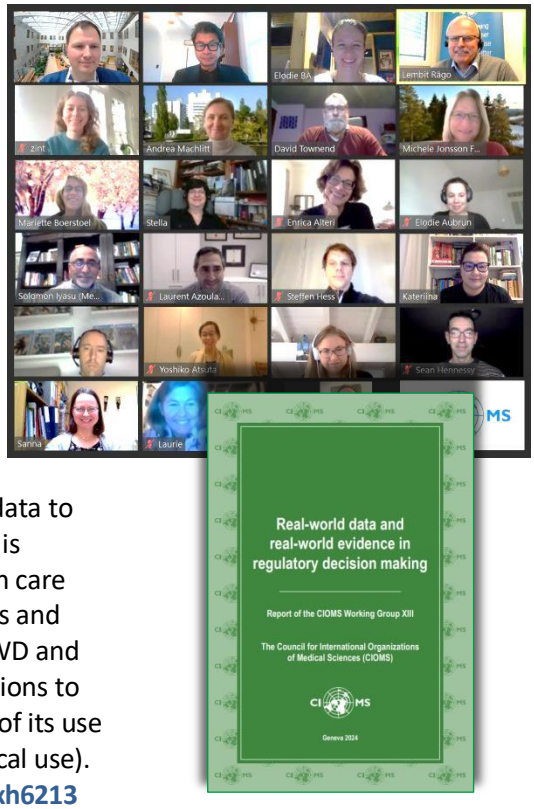
Just published

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

Report of CIOMS Working Group XIII



(**Right**) The Working Group, at its online meeting in December 2020. The group met almost exclusively online due to the COVID-19 situation.

It is with great pleasure that we announce the publication of this much anticipated CIOMS Working Group report, which was met with great interest (see the download statistics on page 8)

Real-world data—for example from electronic health records or registries—are increasingly being used to complement clinical trial data to support safety and efficacy claims for medicines. This CIOMS report is intended for medicinal product regulators, healthcare payers, health care and medicinal products industries, researchers, bioethicists, patients and health care professionals. It informs discussions about the use of RWD and RWE for regulatory and health care decision making, including decisions to make a product available for use (authorisation), to cover the costs of its use (reimbursement), and to use a product for a particular patient (clinical use).

☞ **The report is freely available here: https://doi.org/10.56759/kfxh6213**

Severe cutaneous adverse reactions (SCAR)

Draft CIOMS Working Group report published for comment

(**Below**) This is the second CIOMS report on organ system-related adverse events (the first one was on drug-induced liver injury, DILI).

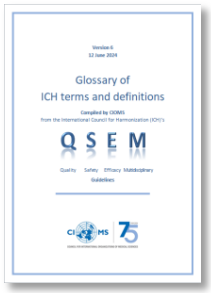
Skin is the most commonly affected organ by adverse drug reactions. Although most of these reactions are not severe, and very few are fatal, SCAR needs to be promptly recognized and treated. This draft CIOMS Working Group report provides a global consensus reference for regulators, patient organizations, scientists, industry and clinicians.

The comments received during the six-week public consultation period are now being addressed by the Working Group's editorial team.

☞ **Draft Working Group report on Severe cutaneous adverse reactions (SCAR), 29 April 2024**

CIOMS Glossary of ICH terms and definitions: Version 6

Living document



The CIOMS ICH glossary brings together terms and definitions from the guidelines of the International Council for Harmonisation (ICH). Version 6 newly includes definitions from:

- **E2D(R1)**. Post Approval Safety Data Management: Definition and Standards for Expedited Reporting. Step 2 (draft), 5 February 2024.
- **Q3C(R9)**. Guideline for Residual Solvents. Step 4 (final), 24 January 2024.
- **M14**. General Principles on Plan, Design and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines. Step 2 (draft), 21 May 2024.
- **M12**. Drug Interaction Studies. Step 4 (final), 21 May 2024.

☞ **The glossary is freely available at: https://doi.org/10.56759/eftb6868,** or from the ICH website here.

CIOMS meetings

Working Groups

☞ List of CIOMS Working Groups

In-person meeting

Pharmacoepidemiology for public health

CIOMS Working Group XV: 3rd Meeting, Paris (France), 24–25 May 2024

COVID-19 has shown that public health is impacted by many factors, such as animal diseases, environmental damage, and people's perceptions and behaviours. Also, new technologies are being launched and unprecedented amounts of medical data generated, adding layers of complexity to clinical research. The CIOMS Working Group XV will recommend some efficient approaches to making better use of pharmacoepidemiology to answer the most pertinent questions about the effects of medicines.

☞ **Read more in the group's concept paper.**

(**Above**) How can we best determine the benefits and risks of medicines in real-world settings? At its 3rd Meeting, the CIOMS Working Group XV continued to discuss its proposed guidance to support decision-making on medical products.

Virtual meetings

Real-world data and real-world evidence in regulatory decision making
19th Meeting, 8 April 2024

Education for health professionals participating in medicines development
8th Meeting, 7–14 May 2024

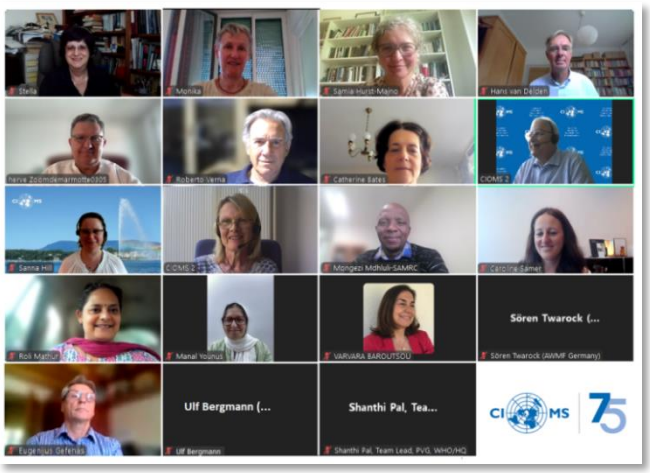
CIOMS General Assembly

27th Session

25 June 2024 (virtual meeting)

The CIOMS General Assembly heard an update on the CIOMS activities in 2023 and discussed the proposed programme for 2024. The financial reports and 2024 budget were presented and approved. Dr Varvara Baroutsou was confirmed as new Executive Committee member representing the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP).

☞ **Read more about CIOMS governance**



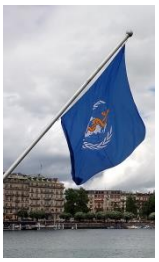
CIOMS@ International events

World Health Assembly

27 May – 1 June 2024, Geneva (Switzerland)

The Seventy-seventh World Health Assembly (WHA77) made decisions on climate and health, preparedness and response to health emergencies, anti-microbial resistance, access to transformative tools, a range of disease-related topics, and the transformation of WHO itself.

CIOMS is in official relations with WHO and was represented at WHA77 by its President and Secretary-General. WHO experts participate in most CIOMS Working Groups, and CIOMS reports have informed WHO work; a recent example is the draft WHO guidance on best practices for clinical trials.



All WHA77 documents

ICH Assembly

4-5 June 2024, Fukuoka (Japan)

Image from: www.ich.org

CIOMS Secretary-General Lembit Rägo participated in the Assembly meeting of the International Council for Harmonisation (ICH), in which CIOMS is an observer. He also presented the recent CIOMS Working Group report on MedDRA Labeling Grouping (MLG) to the ICH MedDRA Management Committee, for a decision on a follow-up on the report recommendations.

The ICH harmonised guidelines on medicines quality, safety and efficacy serve as a basis for legislation in many countries globally. CIOMS has been contributing to ICH by hosting an Expert Working Group on Standardised MedDRA Queries (SMQ) and by maintaining a glossary of ICH terms and definitions (see page 2).

ICH Press release, 12 June 2024

Medical student delegation visits CIOMS

28 May 2024, Geneva (Switzerland)

While attending the Youth PreWHA (Pre-World Health Assembly) in Geneva, a group of fifteen students from the International Federation of Medical Students Association (IFMSA) visited CIOMS and were given an overview of its mission and work by the Secretary-General. In a lively Q&A session, they explored topics such as how CIOMS Working Groups are constituted, the challenges of conducting research in low-resource settings and the uses of electronic health records for research.

(**Above**) The IFMSA delegation during its visit. The students hailed from diverse countries such as Venezuela, Hong Kong, Spain, India, Morocco, Ukraine and Mexico. They were happy to hear about the CIOMS Student Award programme, and also to leave with some CIOMS publications in hand.

Other events in brief

ANVISA 25th Anniversary Workshop

21 May 2024, Brasilia (Brazil)

(**Left**) Dr Lembit Rägo's recorded speech on the future of medicines regulation set the tone for a workshop hosted by the regulatory authority of Brazil.

World Congress on Pharmaceutical Research and Toxicology

30-31 May 2024, Geneva (Switzerland)

(**Left**) At this event the CIOMS Secretary-General delivered a keynote address and shared his expertise on some recent CIOMS Working Group topics.

CIOMS@ International events (continued)

Save the date. Meet us at these annual meetings of our member organizations:

International Society of Pharmacoepidemiology (ISPE)

24– 28 August
Berlin (Germany)

2024 ISPE ANNUAL MEETING

Meeting webpage

International Society of Pharmacovigilance (ISoP)

1–5 October
Montreal (Canada)

2024 ISoP ANNUAL MEETING MONTREAL

Meeting webpage

News roundup

New regulatory guidance

EMA — European Medicines Agency

Real-world data

Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence. 3 May 2024. Draft for public comments. Closing date: 31 August 2024.

Advanced therapy medicinal products

Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials. Draft guideline, 25 March 2024. Comment period closed on 31 May 2024.

FDA — U.S. Food and Drug Administration

Real-world evidence

Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products. Draft guidance, March 2024.

Ethnicity data in clinical trials

Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products. Draft guidance, January 2024. Revises guidance issued in October 2016.

Informed consent guidance

Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards. Draft guidance, March 2024.

International initiatives

Europe

One Health

Five European agencies (ECDC, ECHA, EEA, EFSA and EMA) have published a joint frame–work for cooperation to support the One Health agenda in the European Union (EU). One Health recognises the complex interplay between human, animal and plant health, food safety, the climate crisis and environmental sustainability.

EMA News, 7 May 2024.

WHO — World Health Organization

Antimicrobial resistance (AMR)

A new report by the Global Leaders Group on AMR urgently recommends some bold actions to ensure equitable access to anti-infective treatments, vaccines, diagnostics and waste management tools.

WHO Press release, 4 April 2024.

Global Leaders Group report. April 2024.

Also read the **CIOMS special newsletter on Fighting AMR** (November 2022)

WHO-Listed Authorities (WLAs)

A total of 36 regulatory authorities are now designated as 'WHO-Listed Authorities' (WLAs) that can be relied on to provide regulatory assurance of the quality, safety and efficacy of medical products. The list of WLAs can be downloaded here.

WHO news release, 20 May 2024.

News roundup (continued)

Focus on:
Artificial intelligence (AI)

Living Guidelines on the responsible use of generative AI in research

The European Commission has proposed a set of recommendations to foster the adoption of the technology in a responsible manner. The research community is encouraged to provide feedback.

☞ Living guidelines | Fact sheet
☞ Feedback form

Perspectives from the Global Forum on Bioethics in Research (GFBR)

This recent publication reports on outcomes from the GFBR, held in Cape Town, South Africa in November 2022. It highlights several innovations, as well as areas in need of urgent attention to strengthen research ethics and governance leadership.

☞ Shaw J, Ali J, Atuire CA, et al. **Research ethics and artificial intelligence for global health: perspectives from the global forum on bioethics in research.** BMC Med Ethics. 2024 Apr 18;25(1):46. doi: 10.1186/s12910-024-01044-w.

Opportunities for input

As identified by the U.S.-based non-profit foundation GE2P2 Global in its Public Consultation Watch. https://ge2p2-center.net/2024

AI code of conduct framework

☞ Adams L, Fontaine E, Lin S, et al. (editors). **Artificial intelligence in health, health care and biomedical science: An AI code of conduct framework principles and commitments.** Discussion draft. National Academy of Medicine, Washington, DC. doi: 10.31478/202403a.

Catalogue of tools and metrics for trustworthy AI

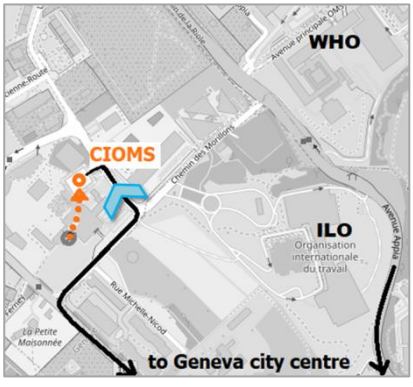
☞ **Contribute to the catalogue of the OECD.AI** Policy Observatory, a forum for governments and countries of the Organization for Economic Cooperation and Development (OECD).

Evaluating digital technologies

☞ **International Science Council. A framework for evaluating rapidly developing digital and related technologies: AI, large language models and beyond.** – To join the discussion, use the online form at the end of the webpage.

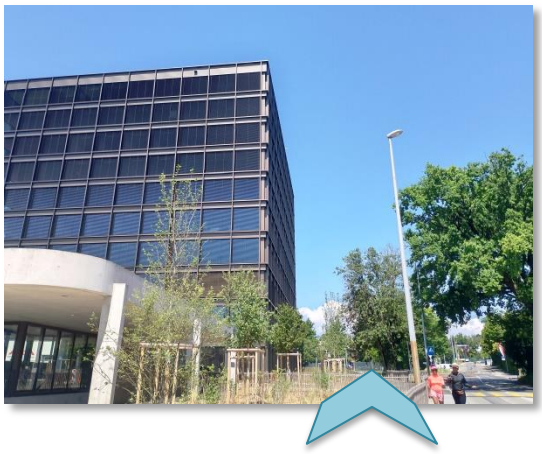
CIOMS Secretariat news

We have moved!



(**Left**) Our new offices are just 100 m from the old ones, which will soon be demolished.

(**Right**) We are now on the third floor of Kyoto House.



Images from: www.openstreetmap.org and https://kyoto-greenvillage.ch

CIOMS cited

Scientific journals

Beninger P. **Pharmacovigilance: A Cauldron of Old and New**. Clin Ther. 2024 Jun 18:S0149-2918(24)00132-2. doi:10.1016/j.clinthera.2024.05.011

De Abreu Ferreira R, Zhong S, Moureaud C, et al. **A Pilot, Predictive Surveillance Model in Pharmacovigilance Using Machine Learning Approaches**. Adv Ther. 2024;41: 2435–2445. doi:10.1007/s12325-024-02870-5

Hurst DJ, Cooper DKC. **The importance of public engagement in clinical xenotransplantation.** Health Care Sci. 2024; 1–7. doi:10.1002/hcs2.91

Kurihara C, Kerpel-Fronius S, Becker S, et al. **Declaration of Helsinki: ethical norm in pursuit of common global goals.** Front. Med. 2024;11:1360653. doi: 10.3389/fmed.2024.1360653

Ravinetto R, Adhiambo J, Kimani J. **Research ethics preparedness during outbreaks and public health emergencies: Focus on community engagement**. Research Ethics [Online first]. doi: 10.1177/17470161241254169

Segal AE, Wendler DS. **The Normative Power of Consent and Limits on Research Risks**. Ethic Theory Moral Prac. 2024. doi: 10.1007/s10677-024-10441-4

Seylani A, Galsinh AS, Tasoula A, et al. **Ethical considerations for the age of non-governmental space exploration**. Nat Commun. 2024 Jun 11;15(1):4774. doi: 10.1038/s41467-023-44357-x

ShamaeiZadeh PA, Villamizar Jaimes C, Deloria Knoll M, et al. **Landscape review of active vaccine safety surveillance activities for COVID-19 vaccines globally**. Vaccine: X. 2024;18;2024:100485. doi:10.1016/j.jvacx.2024.100485

Simonetti A, Colilla S, Edwards B, et al. **Key Opinion Leaders' Interviews to Inform the Future of Benefit-Risk Planning in the Medical Total Product Life Cycle of Global Pharmaceutical and Medical Device Organizations**. Drug Saf. 2024 Jun 1. doi: 10.1007/s40264-024-01442-4

Books

Bull S, Parker M, Ali J, et al. **Research Ethics in Epidemics and Pandemics: A Casebook**. Public Health Ethics Analysis, vol 8. Springer, Cham. 2024.

Schroeder D, Chatfield K, Chennells R, et al. **Vulnerability Revisited. Leaving No One Behind in Research**. SpringerBriefs in Research and Innovation Governance. Springer, Cham. doi:10.1007/978-3-031-57896-0

CIOMS guidance implemented

The Pan American Health Organization (PAHO) is assessing the national research ethics systems in Latin America and Caribbean countries,[1] using an assessment tool [2] that is largely based on CIOMS guidelines.[3] PAHO and the national health authorities then co-organize training sessions for research ethics committees in the respective countries. The legal instruments that govern research are drafted and revised, stating that the country formally adopts the CIOMS international ethical guidelines in the most updated version.

(**Right**): Carla Saenz and Sarah Carracedo during a PAHO webinar held earlier this year. According to Carla it could be said that "**a new era is starting in the region, where "CIOMS is the law".**

[1] Aguilera B, Carracedo S, Saenz C. **Research ethics systems in Latin America and the Caribbean: a systemic assessment using indicators**. Lancet Glob Health. 2022 Aug;10(8):e1204-e1208. doi:10.1016/S2214-109X(22)00128-0.

[2] Pan-American Health Organization (PAHO). **Tool for the accreditation of research ethics committees**. Washington, D.C.: PAHO; 2024. Available at: https://iris.paho.org/handle/10665.2/58904

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https://cioms.ch

1 April – 25 June 2024

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180 countries

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Ongoing CIOMS Working Groups (WG)

Meeting minutes are published on the groups' webpages.

- Pharmacoepidemiology for public health (WG XV)
- Artificial intelligence in pharmacovigilance (WG XIV)
- Educational standards for health professionals participating in medicines development
- Severe cutaneous adverse reactions (SCAR)
- Benefit-risk balance for medicinal products (WG XII)

Completed

- Real-world data and real-world evidence in regulatory decision making (WG XIII)

Top ten CIOMS publications

1 April– 25 June 2024

		⭳ Downloads
30/5/2024	Real-world data and real-world evidence in regulatory decision making	1626
2024	Living document: Glossary of ICH terms and definitions (Versions 5 and 6)	1322
2024	Introduction to MedDRA labeling grouping (MLG)	578
2023	CIOMS cumulative glossary, with a focus on pharmacovigilance (Version 2.1)*	361
2010	Practical aspects of signal detection in pharmacovigilance †	266
2016	International ethical guidelines for health-related research involving humans ‡	254
2020	Drug-induced liver injury (DILI)	243
2016	Development and rational use of standardised MedDRA queries (SMQs), 2nd Edition§	222
2014	Practical approaches to risk minimisation for medicinal products	205
2006	Development safety update report (DSUR): harmonizing the format and content…	197

* Also available in Korean

† Also available in Chinese

‡ Also available in: Arabic, Chinese, French, Japanese, Korean, Polish, Portuguese, Russian, Spanish, Ukrainian

§ Also available in Japanese

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