What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH | December 2023 | **Newsletter** | # 44

In this newsletter

CIOMS Working Group news

Just published:

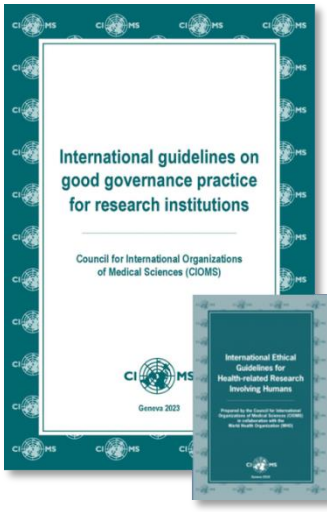
(**Above**) The Working Group, at its final meeting in August/September 2023

International guidelines on good governance practice for research institutions

Scientific research is essential for the health and well-being of people around the world, and is becoming ever more important for humanity to face current and future health emergencies. But scientific studies can only be effective if they are done in compliance with existing high ethical and scientific standards.

Many professional and regulatory guidelines have been adopted in recent decades, mostly focusing on individual researchers' responsibilities. But to what extent do they have the required resources at their workplace? The new CIOMS guidelines describe the existing standards and best practices in the field of health-related research, and offer detailed and specific guidance on how to implement them at institutional level.

☞ **International guidelines on good governance practice for research institutions.** CIOMS Working Group report. Geneva, Switzerland: Council for International Organizations of Medical Sciences (CIOMS), 2023. Freely available at: https://doi.org/10.56759/hslk3269



(**Above**) The new Working Group report complements the 2016 CIOMS International ethical guidelines on health-related research involving humans; which are widely used as a standard for good quality, ethical research.

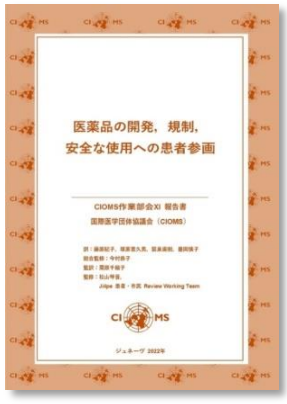
Images by Bonnie Henderson & ID12019 from Pixabay

(**Left**) Research is not only done at dedicated centres, but also at institutions that do not consider research as their primary mission, such as universities or hospitals. These may find the guidelines especially useful.

Japanese translation of the CIOMS guidance on patient involvement

The CIOMS Working Group XI report on *Patient involvement in the development, regulation and safe use of medicines* is now available in Japanese as a pre-print version on the website of the journal *Rinsho Hyoka* (*Clinical Evaluation*). The final print version, with minor corrections and format changes, will be posted at the same address.

Patients and consumers in Japan can participate in the approval of medicines. The translation makes the CIOMS guidance accessible to them in their own language.



CIOMS Working Group meetings

☞ All Working Groups

In-person meetings

Fourth quarter of 2023

18th meeting; Geneva (Switzerland), 4–5 October 2023
First face-to-face meeting of this group
Nine participants joined online

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

CIOMS Working Group XIII

This group published its draft report for comment in June 2023. The draft generated considerable interest, attracting more than 900 comments and questions from commentators all over the world. At their 18th meeting—their first to be held in person—the group members discussed the input received. Their decisions will be taken forward by the group's Editorial Committee in finalizing the report. The full meeting minutes are available on the Working Group's webpage.

Pharmacoepidemiology for public health

CIOMS Working Group XV

Surveillance for adverse effects of medical products has become a very complex task: science and technologies are evolving, expectations of regulators, health care funders and patients must be met, and global public health is becoming increasingly fragile due to environmental and man-made challenges. The CIOMS Working Group XV will look into the best ways to apply current and new approaches to pharmacovigilance.

First meeting
Geneva (Switzerland), 2–3 November 2023
Eight participants joined online

Virtual meetings

Fourth quarter of 2023

12 October 2023	26 October 2023	8 November 2023	20 November 2023
Benefit-Risk Balance for Medicinal Products	**Education and Training for Health Professionals participating in medicines development**	**Artificial Intelligence in Pharmacovigilance**	**Benefit-Risk Balance for Medicinal Products**
WG XII	6th meeting	WG XIV	WG XII
11th meeting		6th meeting	12th meeting

CIOMS@ International events

IMDRF 2023

Berlin (Germany), 25–26 September 2023

At the invitation of the Global **D**iagnostic Imaging, Healthcare **I**T & Radiation **T**herapy **T**rade **A**ssociation (DITTA), CIOMS Secretary-General Lembit Rägo attended the 24th session of the International Medical Device Regulators Forum (IMDRF). At a side event he introduced the DITTA leadership to the work of CIOMS and answered questions.

☞ **Conference website**

World Vaccine Congress Europe

Barcelona (Spain), 16–19 October 2023

This event is the largest, most established meeting dedicated to vaccines, with a record 2000+ participants from science, governments and industry attending in 2023. CIOMS Secretary-General Lembit Rägo introduced the draft report of the CIOMS Working Group XIII on Real-world data and real-world evidence in regulatory decision-making.

☞ **Congress website**

Images from Congress website

ICH Assembly meeting

Prague (Czech Republic), 31 October–1 November 2023

CIOMS is an observer in the International Council for Harmonisation (ICH) and was represented at the Assembly meeting by Secretary-General Lembit Rägo. Delegates were updated on new developments, including the signature of a Memorandum of Understanding with the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

☞ **ICH Press release, 8 November 2023** | ICH Meetings > **Assembly** (agenda, minutes)

Note: Since 2022 CIOMS maintains a Glossary of ICH terms and definitions from across ICH guidelines on its website.

EUPV 2023

Virtual, 27–28 November 2023; Milan (Italy), 1 December 2023

CIOMS was again represented prominently in this year's **European Pharmacovigilance Congress** (EUPV 2023). CIOMS President Hervé Le Louët introduced the virtual session on 'Risk Communication' while CIOMS Secretary General Lembit Rägo chaired the opening session on 'Evolving Pharmacovigilance Strategies' in Milan.

☞ **Congress website**

Image courtesy of event organisers

28th Annual Swiss Symposium in Pharmaceutical Medicine

Zurich (Switzerland), 29 November 2023

This event focused on Optimising Patient Engagement and Ensuring Access to Treatment. CIOMS Secretary-General Lembit Rägo presented the CIOMS Working Group XI report on Patient involvement.

☞ **Meeting website**

Images from meeting website

CIOMS@ International events (continued)

WHO Global Clinical Trials Forum

Geneva (Switzerland), 20 - 21 November 2023

This event served to develop a joint vision and exchange experiences on strengthening clinical research capabilities in line with the World Health Assembly resolution WHA75.8. Participants called for several priority actions to strengthen the clinical trials ecosystem.

In July 2023 WHO had called for comments on a draft guidance document on strengthening clinical trials. The draft is partly based on the 2021 CIOMS consensus report on Clinical research in resource-limited settings (2021) and the CIOMS International ethical guidelines for health-related research involving humans (2016). Elements from the new CIOMS International guidelines on good governance practice for research institutions are also to be included.

(**Right**) Among the participants were Dominique Sprumont, Andreas Reis, Roli Mathur and Nathalie Strub-Wourgaft, all of whom contributed to one or more of the above-mentioned CIOMS guidelines.

CRGo World Conference 2023

Hong Kong / Virtual, 29 November 2023

CIOMS Working Group chair Dominique Sprumont attended the Clinical Research Governance (CRGo) World Conference & International Clinical Trial Center Network Symposium 2023. He took the occasion to announce the release of the CIOMS *International guidelines on good governance practice for research institutions* (see page 1). The conference marked the 25th anniversary of the University of Hong Kong's Clinical Trials Center, which is directed by CIOMS Working Group member Henri Yau.

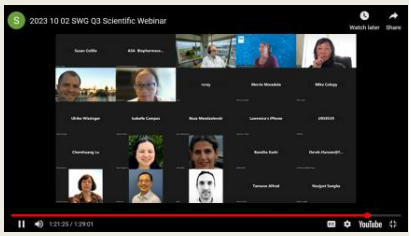
☞ **Conference website**

Webinars

Biopharmaceutical safety statistics

Scientific webinar, 2 October 2023

CIOMS Working Group XII members Hong Yang and Leo Plouffe presented the group's draft report on Benefit-Risk Balance for Medicinal Products at the third quarterly scientific webinar of the American Statistical Association (ASA)'s Safety Working Group. The discussion focused on how to align and improve the ASA Safety group's deliverables on benefit-risk assessment planning in line with the CIOMS work.



☞ **Webpage** | **Recording**

Ethical Innovation for Global Health

Book launch, 4 and 6 December 2023

See also: https://cioms.ch/webinars/

This webinar served to introduce a new book about research ethics in times of pandemics. In Part 2, CIOMS Secretary-General Lembit Rägo presented Chapter 10, which gives an overview of the history and activities of CIOMS in relation to bioethics (for details see page 7).

☞ **Webinar flyer** | **Part 1 recording** | **Part 2 recording**

☞ Kurihara C, Greco D, Dhai A (editors). **Ethical Innovation for Global Health.** Springer Nature Singapore Pte Ltd. 2023. doi:10.1007/978-981-99-6163-4 (not open-access)

News roundup

Based on an image by Nicolás from Pixabay

Focus on: Regulatory reliance

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

Benefit-risk assessment guidance

The U.S. FDA has released its final guideline on Benefit-Risk Assessment for New Drug and Biological Products. The guidance discusses how patient experience data, sponsors' development programmes and information presented in the marketing application may be used to inform the benefit-risk assessment, and also considers factors that inform decision-making in the postmarket setting.

☞ **Benefit-Risk Assessment for New Drug and Biological Products.** Guidance for Industry. October 2023.

WHO — World Health Organization

Regulating artificial intelligence

WHO has published a new guidance document on how to regulate artificial intelligence (AI) to make use of its potential while mitigating its risks. The publication outlines the main principles that national or regional governmental authorities can use as a basis to develop new guidelines or to adapt existing ones.

AI can help to strengthen clinical trials, improve diagnosis, treatment, self-care and person-centred care, and can supplement the knowledge, skills and competencies of health care professionals. However, it also presents serious risks of unethical data collection, cybersecurity threats and amplifying biases or misinformation.

☞ WHO. **Regulatory considerations on artificial intelligence for health.** 2023.

☞ Medscape. **WHO offers recommendations for AI guidelines in healthcare.** 14 November 2023.

WHO-listed authorities (WLA)

Health regulatory authorities are increasingly looking to rely on each other's work so as to make optimal use of limited resources. WHO has developed a framework to designate so-called WHO-listed authorities (WLA), identifying them as operating at an advanced level of performance, meaning that they meet WHO standards and other internationally recognized standards and practices.

The first three WLAs have now been publicly listed on the WHO website. They are the regulatory authorities of the **Republic of Korea** (for medicines and vaccines); **Singapore** (medicines); and **Switzerland** (medicines and vaccines). This supplements WHO's list of transitional WLAs of 54 bodies formerly known as 'stringent regulatory authorities' in the more procurement-oriented concept that was used before the WLA framework came into being.

Note: The **WLA technical advisory group** (TAG-WLA) provides independent, strategic, and technical advice to WHO regarding this initiative. CIOMS Secretary-General Lembit Rägo is one of its 14 members.

SAHPRA — South African Health Products Regulatory Agency

South African reliance guideline

The South African regulatory authority has released its draft reliance guideline for review of marketing authorization applications and variations. Three different pathways are proposed for relying on other authorities' assessments. The draft lists examples of recognized regulatory authorities (RRAs), together with the documents that would comprise a complete assessment for each.

SAHPRA is currently negotiating recognition agreements with RRAs, and will publish a framework for the practical implementation of each agreement once it is concluded.

☞ SAHPRA. **Reliance guideline.** Draft, 2 November 2023.

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Sulaieva ON, Artamonova O, Dudin O, et al. **Ethical navigation of biobanking establishment in Ukraine: learning from the experience of developing countries.** J Med Ethics. 2023;jme-2023-109129. doi: 10.1136/jme-2023-109129

Vemula GK, Badale P, Mavrogenis P, et al. **A Risk-Based Approach for Safety Case Follow-up of Adverse Event Reports in Pharmacovigilance** [online ahead of print, 2023 Nov 3]. Adv Ther. 2023;10.1007/s12325-023-02699-4. doi: 10.1007/s12325-023-02699-4

Book chapter

Rägo L, Zweygarth M. **CIOMS Research Guidelines: Considering the Needs of Developing Countries**. Chapter 10. In: C. Kurihara et al. (eds.). Ethical Innovation for Global Health. Springer Nature Singapore Pte Ltd. 2023. https://doi.org/10.1007/978-981-99-6163-4_10 **(not open-access)**

This chapter gives an overview of the history and activities of the Council for International Organizations of Medical Sciences (CIOMS) in the areas of research ethics, medicines development and medicines safety (pharmacovigilance). Three specific CIOMS guidelines are then briefly discussed: The 2016 CIOMS/WHO *International ethical guidelines on health-related research involving humans*; the 2021 CIOMS Working Group report on *Clinical research in resource-limited settings*; and the 2022 report of the CIOMS Working Group XI on *Patient involvement in the development, regulation and safe use of medicines*.

Introductory webinar: see **page 2**

CIOMS Secretariat news

Find us on the web ☞ https://cioms.ch

1 September–17 December 2023

29 445 visitors from

188 countries

16 896 subscribers

Ongoing CIOMS Working Groups (WG)

Meeting minutes are posted on the groups' webpages.

- Just completed: Good Governance Practice for Research Institutions
- Artificial Intelligence in Pharmacovigilance (WG XIV)
- Educational standards for health professionals participating in med's development
- Severe Cutaneous Adverse Reactions to Drugs (SCARs)
- Real-World Data and Real-World Evidence in Regulatory Decision Making (WG XIII)
- Benefit-Risk Balance for Medicinal Products (WG XII)
- MedDRA Labelling Groupings
- Just started: Pharmacoepidemiology for public health (WG XV)

Top ten CIOMS publications

Downloads

1 September–17 December 2023

2023	Glossary of ICH terms and definitions (Version 4)	841
2023	International guidelines on good governance practice for research institutions	779
2023	CIOMS Cumulative glossary, with a focus on pharmacovigilance (Version 2.1)	520
2016	International ethical guidelines for health-related research involving humans*	285
2022	Patient involvement (Working Group XI) **	242
2005	Management of Safety Information from Clinical Trials***	215
2010	Practical Aspects of Signal Detection in Pharmacovigilance	153
2021	Clinical research in resource-limited settings	141
2020	Drug-Induced Liver Injury (DILI)	135
1999	Reporting Adverse Drug Reactions: Definitions of Terms and Criteria for Their Use	118

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

** Also available in Japanese, see page 7 — *** Also available in Chinese

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