What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH June 2023 | **Newsletter** **# 42**

Quick links

Comments invited

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

Draft report of CIOMS Working Group XIII

Today, methods exist for using real-world data (RWD)—e.g. from healthcare claims or mobile phone apps—to study the effects of medicines in very large, diverse patient groups for long periods.

This draft report discusses the strengths and limitations of RWD sources, their foreseeable development, scientific considerations for deriving real-world evidence (RWE) from them, as well as ethical and legal perspectives.

☞ **Draft report | Comment form**

*(**Above**) The three CIOMS Working Groups (WGs) which have published their draft reports for comments during the first quarter of 2023. WG XIII has held all its meetings online.*

Benefit-risk balance for medicinal products

Draft report of CIOMS Working Group XII

Much has changed since 1998, when the CIOMS Working Group IV published its first report on this topic: Products have become more complex, new data sources are used for decision-making, new regulatory pathways have opened up, and the patient perspective has come to the foreground.

The draft report of the CIOMS Working Group XII proposes a structured framework for benefit-risk assessment at every stage of a product's lifecycle.

☞ **Draft report | Comment form**

Public consultation completed

Good Governance Practice for Research Institutions (GGPRI)

Most laws and guidelines require that researchers protect the welfare, rights and dignity of research participants. How best can research institutions equip their staff to meet these obligations? The CIOMS Working Group is finalizing its draft guidance on this topic in light of the comments received.

☞ **Draft report | Working Group webpage**

CIOMS@ **International events**

DIA 2023 Global Annual Meeting

25-29 June 2023; Boston, United States

Members of the CIOMS Working Groups XI and XII presented their groups' work at the annual flagship event convened by the DIA (founded as the Drug Information Association).

- Session 27 June: Benefit-Risk Balance for Medicinal Products: CIOMS Working Group XII report

*(**Above**) CIOMS Working Group XII members Ana-Claudia Ianos, Richard Forshee, Carmit Strauss and Scott Evans, at the DIA session*

- Session 29 June: What CIOMS does, and the guideline on Patient involvement in the development, regulation and safe use of medicines: CIOMS Working Group XI

*(**From top left**) CIOMS Working Group XI members Stella Blackburn, Juan Burgos and Hervé le Louët, and patient representative Alexandra Leijenhorst*

☞ **DIA 2023 Meeting website**

ICH General Assembly

12–13 June 2023; Vancouver, Canada

At its 46th General Assembly, the International Council for Harmonization (ICH) welcomed Egyptian Drug Agency as the first regulatory member from Africa, and the regulatory authority of Nigeria (NAFDAC) joined as an ICH observer. This further expands the global membership of ICH.

☞ **ICH press release, 20 June 2023.**

CIOMS as an ICH observer is represented in ICH by its Secretary-General, Lembit Rägo. Since September 2022 CIOMS is maintaining a Glossary of ICH terms and definitions on its website, an initiative that has been appreciated by ICH constituents and other stakeholders.

ISoP mid-year symposium

1-2 June 2023; Leiden, the Netherlands

The event was hosted by the Netherlands pharmacovigilance centre Lareb. The CIOMS Working Group XI report on Patient involvement was introduced in Session 6, titled 'The role of patients in pharmacovigilance'.

*(**Above**) Three CIOMS Working Group XI contributors were among the speakers at the Symposium. (From left) Linda Härmark (Lareb), Kaisa Immonen (EMA Patient and Consumer Working Party) and Lembit Rägo (CIOMS).*

☞ **ISoP Symposium website**

Save the date

Meet us at these events:

IFPMA 5th Africa Regulatory Conference (AfRC)

12–15 September 2023, online
Languages: English & French

Organized by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), in partnership with AREPI, IPASA, KAPI, LEEM and LIPA.

☞ **Read more**

European Pharmacovigilance Congress (EUPV) 2023

27-28 November 2023; virtual
1 December 2023; Milan, Italy

Annual event organized by the Pharma Education Center (PEC). Speaker abstracts are subsequently published in the *Therapeutic Advances in Drug Safety* journal.

☞ **Read more**

Annual Swiss Symposium in Pharmaceutical Medicine

29 November 2023; Zurich, Switzerland

Organized by the Swiss Association of Pharmaceutical Medicine (SwAPP), around the theme of *Optimising Patient Engagement and Ensuring Access to Treatment.*

☞ **Read more**

WHO World Health Organization

Seventy-sixth World Health Assembly (WHA76)

21–30 May 2023, Geneva, Switzerland

This year's World Health Assembly dealt with a wide range of strategic topics, for example a report on transforming economies to deliver health for all, and a new global strategy on infection prevention and control. Delegates adopted 23 decisions and 19 Resolutions, among them Resolution WHA 76.5 on Strengthening diagnostics capacity.

CIOMS is a non-State actor in official relations with WHO, and followed some of the sessions online.

☞ **WHA76 webpage | All meeting documents**

WHO global health-related news

- Negotiations continue on an intergovernmental pandemic accord and on amendments to the International Health Regulations.
- The WHO mRNA Technology Transfer Hub in South Africa has developed a COVID–19 vaccine candidate product. Facilities in 15 low- and middle-income countries have been identified as technology transfer recipients.
- WHO and the Republic of Korea have agreed to establish a global biomanufacturing training hub, to equip low- and middle-income countries to produce needed vaccines and medicines.
- WHO has published a policy brief titled Global research agenda for antimicrobial resistance in human health. The document aims to inform efforts to address antimicrobial resistance, especially in low-and-middle-income countries.

CIOMS@ WHA76 side events

10th Global Patients Congress (GPC 2023)

19–20 May 2023; Geneva, Switzerland (hybrid event)

The International Alliance of Patients' Organizations (IAPO) held its biennial flagship event on the weekend before WHA76.

*(**Right**) Session 5 opened with a presentation by CIOMS Secretary General Lembit Rägo on the CIOMS XI report on Patient involvement.*

Image: Estelle Jobson, on LinkedIn

☞ **Congress webpage**

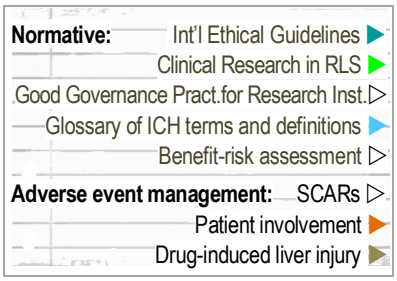
The road to strengthening clinical trials

24 May 2023; Geneva, Switzerland

This event was hosted by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) in order to discuss the implementation of Resolution WHA75.8 on strengthening clinical trials. CIOMS Working Group member Nathalie Strub-Wourgaft was among the speakers, and Secretary-General Lembit Rägo provided copies of the CIOMS report on Clinical research in resource-limited settings (RLS).

*(**Right**) Eight CIOMS initiatives are on WHO's list* collated during the public consultation on Strengthening clinical trials.*

**Download the Excel*



☞ **Event webpage** (includes presentations)

ⓘ Useful resource:

Sharing and reuse of health-related data for research purposes

WHO policy and implementation guidance

Shared health data are a global public health good. With this in mind, WHO has developed a data-sharing policy, along with practical guidance, for its staff who manage health research.

With regard to obtaining consent for collecting and sharing patient data the WHO guidance is based on the principles of the 2016 CIOMS/WHO International Ethical Guidelines for Health-related Research involving Humans. Following the recent launch of WHO's new tuberculosis treatment individual patient data (TB-IPD) platform, the implementing partner has reached out to CIOMS to understand more about how CIOMS guidance is interpreted for parties who are not researchers but are collecting, curating and sharing primary data.

News roundup

ICH International Council for Harmonization

Good Clinical Practice (GCP)

The draft revision 3 of the ICH guidelines for Good Clinical Practice (GCP) takes into account the increasingly diverse clinical trial types, technologies and data sources being used to support regulatory and healthcare-related decision-making.

Given the expanding membership of ICH, the guidelines will have a significant impact worldwide.

☞ **Web:** Efficacy guidelines , E6(R3) EWG
PDF: Draft revised ICH E6(R3) Guideline

▶ Just released: Harmonization of real-world evidence terminology

ICH has released a Reflection Paper for public consultation. Comments are invited until 30 September 2023.

☞ **Web:** ICH Reflection papers, RWE terminology
PDF: International Harmonisation of Real-World Evidence Terminology and Convergence of (…)

EC European Commission

Pharmaceutical legislation reform

To make medicines more available, accessible and affordable., the European Commission has proposed what is to be the largest pharmaceutical legislation reform in twenty years. A new Directive and a new Regulation are to revise and replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases. A Council Recommendation has also been proposed to step up the fight against antimicrobial resistance.

☞ **EC Press release**, 26 April 2023 | Related **links**

EMA European Medicines Agency

Report on PRIority MEdicines scheme

The EMA has analyzed the first five years' experience with its PRIority MEdicines (PRIME) scheme, which supports the development of needed innovative products. These have included technologies such as CAR T-cell therapies, one-time potentially curative gene therapies, rare cancer treatments and an Ebola vaccine. The scheme has helped applicants to bring needed products to market sooner. Areas for improvement have been identified.

☞ **PRIME: Analysis of the first 5 years' experience.**

U.S. FDA United States Food and Drug Administration

Decentralized clinical trials

In decentralized clinical trials, certain activities are conducted outside traditional trial sites, for example at patients' homes or at local health care facilities. This makes participation more convenient and accessible, helping researchers to enrol and retain a meaningfully diverse trial population. The draft guidance makes recommendations for designing and implementing such trials.

☞ **Decentralized Clinical Trials for Drugs, Biological Products, and Devices .**
—**Comments invited** until 1 August 2023

Patient-focused drug development

This is the fourth guidance in the FDA's Patient-Focused Drug Development (PFDD) series. It describes how to select endpoints for regulatory decision-making on new medicines, and how to define what changes in those endpoints would be meaningful for patients.

☞ Patient-Focused Drug Development: **Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making**. Draft Guidance. April 2023.—**Comments invited** until 5 July 2023

Simplified patient leaflets

The U.S. FDA is proposing to require a more concise type of Medication Guide, called Patient Medication Information (PMI), for prescription drug products. A PMI would be a one-page document with standardized format and content.

☞ **Patient Medication Information** (webpage)
—**Comments invited** until 27 November 2023

AI / ML for drug development

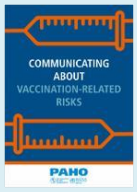
Over the past few years the U.S. FDA has seen a significant increase in drug and biologic application submissions using artificial intelligence (AI) and machine learning (ML) components. The Agency has published a discussion paper to explore next steps for the responsible use of AI/ML in drug development.

☞ Discussion paper and request for feedback. **Using Artificial Intelligence & Machine Learning in the Development of Drug and Biological Products.**
—**Comments invited** until 9 August 2023

CIOMS cited

Book chapters and reports

Arellano L, Alcubilla P, Leguízamo P. **Ethical Considerations in Informed Consent.** Chapter in: Ethics in Scientific Research - New Perspectives. Rijeka, Croatia: IntechOpen; 2023.



Pan American Health Organization. **Communicating about Vaccination-related Risks**. Washington, D.C.: PAHO; 2023. This document seeks to help communications professionals to communicate more effectively about Events Supposedly Attributed to Vaccination and Immunization (ESAVI). It cites case studies from the CIOMS Guide to Vaccine Safety Communication. ▶

Williams B et al. **The Ethics of Controlled Human Infection Model Studies for Mitigating Pandemic Risks**. Report. Oxford: UK Pandemic Ethics Accelerator, 2023.

Journal articles

Akyüz K, Goisauf M, Chassang G, et al. **Post-identifiability in changing sociotechnological genomic data environments**. BioSocieties. 2023, online first 28 March. https://doi.org/10.1057/s41292-023-00299-7

Bahri P, Bowring G, Edwards BD, et al. **Communicating for the Safe Use of Medicines: Progress and Directions for the 2020s Promoted by the Special Interest Group of the International Society of Pharmacovigilance**. Drug Saf 46, 517–532 (2023). https://doi.org/10.1007/s40264-023-01285-5

Buchanan J, Li M. **Important Considerations for Signal Detection and Evaluation**. Ther Innov Regul Sci. 2023 Apr 17. https://doi.org/10.1007/s43441-023-00518-0

Dietrich J, Kazzer P. **Provision and Characterization of a Corpus for Pharmaceutical, Biomedical Named Entity Recognition for Pharmacovigilance: Evaluation of Language Registers and Training Data Sufficiency**. Drug Saf. 2023 Jun 20. https://doi.org/10.1007/s40264-023-01322-3

Kurihara C, Crawley FP, Baroutsou V, et al. **The continuation of clinical trials in times of war: A need to develop ethics and situationally adaptive clinical research guidelines.** Front Med (Lausanne). 2022 Sep 16;9:966220. https://doi.org/10.3389/fmed.2022.966220.

Norberg Wieslander K, Höglund A T, Frygner-Holm S, et al. **Research ethics committee members' perspectives on paediatric research: a qualitative interview study**. Research Ethics. 2023. Online first, 12 June 2023. https://doi.org/10.1177/17470161231179663

Okun S, Hanger M, Browne-James L, et al. **Commitments for Ethically Responsible Sourcing, Use, and Reuse of Patient Data in the Digital Age: Cocreation Process**. J Med Internet Res. 2023 May 5;25:e41095. https://doi.org/10.2196/41095.

Prasanna Parimi V, Kumar Kedia A, Ravindran V. **Personal data in biomedical research**. J R Coll Physicians Edinb. 2023 Jun 9:14782715231175001. https://doi.org/10.1177/14782715231175001

Samara C, Garcia A, Henry C, et al. **Safety Surveillance During Drug Development: Comparative Evaluation of Existing Regulations**. Adv Ther. 2023 Apr 5;40(5):2147–85. https://doi.org/10.1007/s12325-023-02492-3.

Sullivan T, Zorenyi G, Feron J, et al. **A Structured Benefit-Risk Assessment Operating Model for Investigational Medicinal Products in the Pharmaceutical Industry.** Ther Innov Regul Sci. 2023 Apr 1. Epub ahead of print. https://doi.org/10.1007/s43441-023-00508-2

Younus MM, Alkhakany M, Bahri P, et al. **The ISoP PatEG-SIG* for Promoting Patient Engagement in Pharmaco-vigilance: A Change of Paradigm is Needed.** Drug Saf (2023). https://doi.org/10.1007/s40264-023-01313-4
* International Society of Pharmacovigilance Special Interest Group on patient engagement

DIA Global Forum, March 2023 issue. Special section: Clinical research in Ukraine*

▷ Kurihara C, Dobrova V, Crawley FP, et al. **Ethical Considerations: Clinical Research in Wartime Ukraine and Beyond**.

▷ Kerpel-Fronius S. **Ethical Considerations on Clinical Trial Participation and Management in Wartime Conditions**. Perspective from the IFAPP Ethics Working Group.

Feature article

Garrigan C, Levitan B. **Industry implementation of structured, patient-focused benefit-risk assessment.** RF Quarterly. 2023;3(1):31-41. Published online 22 March 2023.

In memory of

Sev Solomon Fluss

It is with great sadness that we announce the passing of our colleague of many years, Sev Fluss, at the age of 88 years after a long illness.

Sev was born in Poland, but grew up in Scotland. He studied at the Universities of Edinburgh, Cambridge and Wisconsin, and then worked for five years at an institution in Cambridge, England, dealing with information on plant breeding and genetics. By 1965 he had a good knowledge of several languages, notably French, Spanish, German and Russian. In that year, he was selected for a post in the WHO Health Legislation Unit, where he successively worked as junior editor, senior editor, Responsible Officer and Chief of the Unit until 1995.

In 1988, when the late Dr Hiroshi Nakajima was elected Director-General (DG) of WHO, Sev became one of his speechwriters and was called upon to draft speeches delivered in places as diverse as the Elysée Palace in Paris, the Kremlin, and the Presidential Palace in Damascus. He was also responsible for preparing the briefing documents used by the DG during his official visits to WHO Member States.

During his last two years at WHO Sev worked on human rights issues in the Office of Health Policy in Development. In 1997 he retired from WHO and joined CIOMS as Special Adviser, then as Senior Adviser. He made invaluable contributions to the ongoing CIOMS projects, for example by proofreading and providing edits to the 2016 International Ethical Guidelines for Health-related Research involving Humans.

*(**Above**) Sev, during the 2014 CIOMS Executive Committee meeting. Up until very recently he continued to assist CIOMS with various editing jobs, proving his undiminished sharp mind and his gift of concise expression. In 2019 he regaled us with tales from his extra-ordinary career in an interview for the CIOMS 70th Anniversary newsletter—extremely modest but with a twinkle in his eyes.*

Our annual team lunches by the lakeside will now have to go on without him. We will miss him.

Image by Hanneke Visschers from Pixabay

Among his many honours, Sev was a Member of the International Council of Environmental Law, one of the Governors of the World Association for Medical Law for many years, and an Honorary Member of the Czech Medical Association. From 1996-99 he was a Special Professor in the Faculty of Medicine and Health Sciences of the University of Nottingham.

During his years at WHO and then CIOMS, Sev has authored and co-authored numerous publications. His most-cited papers are on the history and status of the World Medical Association's Declaration of Helsinki, and on the Nuremberg Code adopted following the Nuremberg Doctors' Trial (United States v. Karl Brandt et al., held in 1946-47).

Sev was preceded in death by his wife, Vera. He leaves behind three children and their spouses, five grandchildren, and many relatives and friends all over the world.

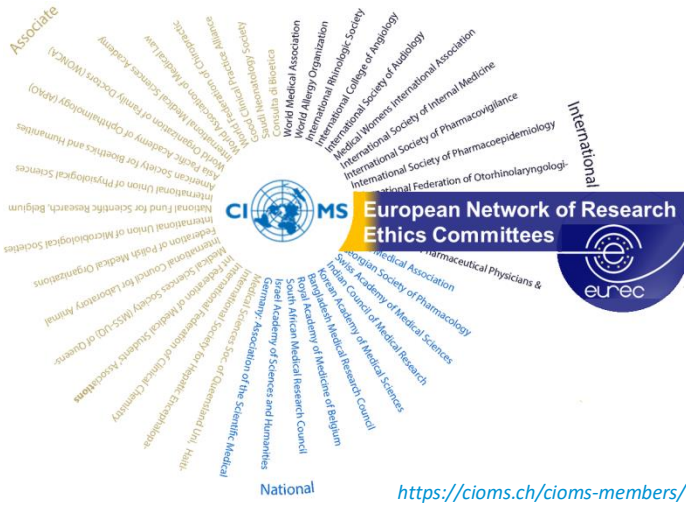
☞ **Death notice, Tribune de Genève**

Sev's memorial site

CIOMS Secretariat news

EUREC joins CIOMS

The European Network of Research Ethics Committees (EUREC) has joined CIOMS as an international member. EUREC brings together national medical Research Ethics Committees (RECs) associations, networks and comparable institutions from the European Union, Norway, Switzerland and the United Kingdom. Founded in 2005, it promotes awareness of REC's working practices, shares knowledge, supports coherent reviews and opinions across Europe, and works to meet new challenges and emerging ethical issues. The network interlinks European RECs with other relevant European bodies in the field of research involving human participants.



https://cioms.ch/cioms-members/

CIOMS and medical students

Informal visit at CIOMS, 22 March 2023

Representatives of the International Federation of Medical Students Associations (IFMSA) visited CIOMS to discuss topics of mutual interest such as the CIOMS annual student award, potential internships for medical students at CIOMS, and plans for a survey to find out what undergraduate students learn about medical product development at different medical schools globally.

IFMSA is an associate CIOMS member. Through its national member organizations it unites 1.3 million medical students from around the globe.

***(Above)**: Yazan Kamal Demaidi (IFMSA/Palestine), Lucía Pérez Gómez (IFMSA/Spain), Lembit Rägo (CIOMS) and Khushman Kaur Bhullar (IFMSA/India).*

XXVIth General Assembly

22 June 2023, virtual meeting

Good progress has been reported at the Twenty-Sixth Session of the CIOMS General Assembly, especially with regard to recent and upcoming publications and growing attention to the CIOMS website. Participants welcomed EUREC as a new CIOMS member (see above) and took a number of strategic decisions.

☞ **https://cioms.ch/governance/**

Gender bias in health research

Meeting report now available

Health research is still largely based on results from male participants, and is often 'blind' to the biological and social particularities of women. How can this be changed? The report of a joint CIOMS/ GENDRO meeting is now available on the CIOMS website.

☞ **Sex and gender considerations in research: the role of research ethics guidelines and research ethics committees.** Meeting report (download).

Ongoing CIOMS Working Groups

Working areas: ▶Bioethics ▶Product development ▶Pharmacovigilance

- **Good Governance Practice for Research Institutions** —Public consultation completed, see page 1
- **Recommended Standards of Education and Training** for Health Professionals Participating in Medicines Development
- **Benefit-Risk Balance for Medicinal Products** (Working Group XII) —Comments invited, see page 1
- **Real-World Data and Real-World Evidence in Regulatory Decision Making** (Working Group XIII)—Comments invited, see page 1
- **Artificial Intelligence in Pharmacovigilance** (Working Group XIV)
- **Severe Cutaneous Adverse Reactions to Drugs** (SCARs)
- **MedDRA Labelling Groupings** to improve safety communication in product labels

The CIOMS Working Group XIV at its 5th Meeting, held in Zurich, Switzerland on 6-7 June 2023, hosted by Takeda. On this occasion a presentation was organized to introduce company staff to CIOMS and its history (see also the CIOMS 70th Anniversary Newsletter)

Find us on the web

Second quarter of 2023 (as of 26 June)

35 965 visitors from

188 countries

13 449 subscribers

Most frequently downloaded publications

1	Glossary of ICH terms and definitions*	1904
2	CIOMS Cumulative glossary, with a focus on pharmacovigilance*	1739
3	Patient involvement (report of Working Group XI)	234
4	International ethical guidelines for health-related research involving humans	218
5	Drug-Induced Liver Injury (DILI)	215
6	Management of Safety Information from Clinical Trials	211
7	Practical Aspects of Signal Detection in Pharmacovigilance	202
8	Clinical research in resource-limited settings	174

* = 'Living documents'

☞**Discover all CIOMS publications**

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