What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH | September 2023 | **Newsletter** | **# 43**

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Recent in-person meetings — Third quarter of 2023

Good governance practice for research institutions

8th Meeting: 31 August - 1 September 2023, Neuchâtel (Switzerland)

The CIOMS Working Group on Good Governance Practice for Research Institutions held its eighth and final meeting at the University of Neuchâtel. The group's draft report was published for comment in April 2023. The participants reviewed the comments received and agreed on additional points to address in the report. An editorial subgroup was formed to finalize the guidelines over the next few months.

Recommended standards of education and training for health professionals participating in medicines development

5th Meeting: 6-7 September 2023, Chavannes-de-Bogis (Switzerland)

The CIOMS Educational Standards Working Group met in person for the second time. The group is looking to give recommendations on the competency-based knowledge on clinical trials and other medicines development-related activities that should form part of health care professionals' education. The group reviewed the draft chapters and agreed on an editorial strategy to complete its report.

Upcoming meetings

4-5 October 2023

Real-World Data & Evidence in Regulatory Decision-Making
CIOMS Working Group XIII
18th Meeting, Geneva (Switzerland)

12 October 2023

Benefit-Risk Balance for Medicinal Products
CIOMS Working Group XII
11th Meeting, virtual

2-3 November 2023

NEW GROUP:
Pharmacoepidemiology
CIOMS Working Group XV
1st Meeting, Geneva

CIOMS@ International events

Scientific events

Pharmacology:
19th WPC 2023

2-7 July 2023, Glasgow (Scotland)

Speakers on CIOMS guidance on Medicines Safety. Top, from left: Lembit Rägo (CIOMS), Raul Andrade (University of Málaga, Spain), Hervé Le Louët (CIOMS) and François Houÿez (EURORDIS-Rare Diseases Europe).

The International Union of Basic and Clinical Pharmacology (IUPHAR) and the British Pharmacological Society welcomed over 2000 participants from 83 countries at the 19th World Congress of Basic and Clinical Pharmacology 2023 (WCP2023) to discuss topics across the spectrum of pharmacology, focusing on collaboration, innovation and discovery. A dedicated session introduced recent CIOMS Guidance on Medicines Safety relating to drug-induced liver injury (DILI), severe cutaneous adverse reactions (SCARS), patient involvement, and benefit-risk assessment.

The 20th congress (WPC2016) will be held in Melbourne, Australia, on 13-18 July 2026.

☞ **https://wcp2023.org/** | **Session webpage**

Severe cutaneous adverse reactions:
SJS TEN 2023

26-27 August 2023, virtual meeting

The work of the ongoing CIOMS Working Group on severe cutaneous adverse reactions to drugs (SCARs) was presented by Working Group co-chair Melissa Reyes at this year's SJS/TEN meeting organized by Vanderbilt University.

SJS/TEN stands for Stevens-Johnson syndrome and toxic epidermal necrolysis, a life-threatening condition mainly caused by medications. The SJSTEN series of meetings brings together survivors, their families, scientists and clinicians, and seeks to support future research in this area.

☞ **Meeting website**

Regulatory meeting

12th WPRA Meeting

2-4 August 2023, Manila (Philippines)

CIOMS was invited to contribute to the Partners' forum session held at the Twelfth Meeting of the Western Pacific Regional Alliance (WPRA) of National Regulatory Authorities for Medical Products. CIOMS Secretary-General Lembit Rägo introduced the lifecycle-based approach to benefit-risk assessment proposed by the CIOMS Working Group XII on Benefit-risk assessment for medicinal products. The group aims to update the work of CIOMS Working Group IV. Its draft report, which has been driven by several international initiatives on benefit-risk assessment, was published for comment in June 2023 and is now being finalized.

☞ **https://wpralliance.org/** | **CIOMS Presentation**

Save the date

Meet us at these events:

16-19 October 2023

24th Annual World Vaccine Congress (WVC) Europe

Barcelona (Spain)

Partnerships and Market Access: CIOMS XIII – RWD and RWE in Regulatory Decision Making

☞ **Congress website**

15-16 November 2023

DIA Clinical Trials in Europe

Virtual meeting

Session 7: Real World Evidence in Regulatory and HTA Decision-Making (draft CIOMS XIII report)

☞ **Conference website**

News roundup

ICH **International Council for Harmonization**

Terminology collaboration

WHO and ICH have announced a new collaboration to connect the terminologies of the WHO International Classification of Diseases (ICD-11) and the ICH Medical Dictionary for Regulatory Activities (MedDRA). This will establish a unified language for sharing and analysis of data on adverse events, with considerable benefits for pharmacovigilance signal detection, thereby helping to improve medical care and policy worldwide.

Resources on the linkages will be freely available on the WHO website under a Creative Commons license (CC-BY-ND), and will also be provided by ICH to MedDRA subscribers.

☞ **ICH Press release, 27 June 2023.**

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

Informed consent guidance

The U.S. FDA has issued an updated guidance document about informed consent. It provides general guidance on the regulatory requirements, discusses the roles of institutional review boards, clinical investigators, sponsors and the regulator, and answers some frequently asked questions.

The guidance supersedes the FDA's 1998 Guide to Informed Consent and finalizes the draft guidance titled "Informed Consent Information Sheet", issued in 2014.

☞ **U.S. FDA: Clinical Trials Guidance Documents**
Final guidance: **Informed consent (PDF)**

Underrepresented populations

Despite pharmaceutical companies' best efforts, certain populations are still not adequately represented in clinical trials. The U.S. FDA has now invited comments on a new draft guidance on when and how data on these populations can be collected in the postmarketing setting. The comment period closes on 10 October 2023.

☞ **Draft FDA guidance:** Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products
Federal register notice

EMA **European Medicines Agency**

Reflection paper on AI

EMA has published a draft reflection paper on the principles of making use of artificial intelligence (AI) and machine learning (ML) at all steps of a medicines' lifecycle, from drug discovery to the post-authorisation setting. Comments are invited on the draft paper, and on the opportunities and risks of AI in the field of medicines (see also below). The closing date for comments is 31 December 2023.

The reflection paper is part of a set of initiatives aiming to develop capacity for data-driven regulation in Europe, overseen by the Big Data Steering Group (BDSG), whose two co-chairs have both participated in CIOMS Working Groups. The draft reflection paper will be further discussed during a workshop on *Smart regulation in a rapidly evolving world,* scheduled for 20-21 November 2023.

ⓘ "Hot Topic": Artificial intelligence (AI)

The use of ChatGPT in health care

According to itself, 'ChatGPT is designed to interact with users through online conversations, providing consistent and contextually relevant responses to user queries and requests.' A recent article discusses two extreme, opposite views of AI (see below), and proposes some pragmatic questions to be asked when considering the benefits and risks of specific AI applications.

☞ Valiña LG, Mastroleo I. **The ethical and scientific challenges of ChatGPT in health.**

Utopianism: "Deep Medicine: How AI Can Make Healthcare Human Again"

Pessimistic dystopia: "Expert Says There's a 50% Chance AI Will Wipe out Humanity"

NASEM National Academies …

Toward equitable innovation in health and medicine

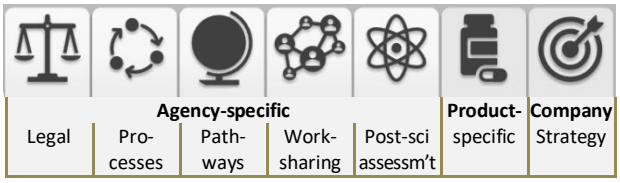
A new report issued by the United States' National Academies of Sciences, Engineering, and Medicine (NASEM) describes a governance framework to advance equitable innovation. It considers different types of equity and how different stakeholders can influence these types of equity at different points in the innovation lifecycle. Practical recommendations are provided and support an ecosystem that will respond to the needs of a broader range of individuals, and is better able to recognize and address inequities as they arise.

☞ **NASEM News release, 22 August 2023**
(with link to the publication)

CIRS **Centre for Innovation in Regulatory Science**

R&D Briefing

The Centre for Innovation in Regulatory Science (CIRS) R&D Briefing number 88 analyzes new drug approvals by six major regulatory authorities over the past ten years, with a focus on orphan designation and facilitated regulatory pathways. The briefing includes figures and details on numbers of approvals, therapeutic areas, timing of submissions and pathways used, and assessment timelines.
It also discusses some of the factors that can affect the outcomes of marketing authorization applications (see below).



☞ **CIRS R&D Briefing 88**
List of approved new active substances

WHO **World Health Organization**

Essential medicines lists

The 2023 essential medicines lists for adults and for children include new medicines for the treatment of multiple sclerosis (a first), cancer, infectious diseases, cardiovascular diseases, and other conditions. There are now 502 medicines on the list for adults and 361 on the list for children. They represent only a small fraction of the number of medicines on the market.

The WHO model lists identify those medicines that satisfy the priority health care needs of a population. They are updated every two years by a WHO Expert Committee, and guide health policy decisions in more than 150 countries.

☞ **Expert Committee report, Executive summary**
Annex 1: 23rd Model List of Essential Medicines (EML)
Annex 2: 9th Essential Medicines List for Children (EMLc)

The WHO webpage has links to electronic lists, with detailed visual statistics on the EMLs of 137 countries:

Global public health news

- At the **UN General Assembly High-level Meetings**, world leaders promised renewed efforts for universal health coverage, pandemic preparedness, and the fight against tuberculosis (TB). WHO launched the TB Vaccine Accelerator Council to support vaccination against TB.
- **Avian influenza** outbreaks in mammal species have caused the tripartite partners (FAO, WHO and WOAH) to call for stepped-up prevention, surveillance and research.
  ☞ WHO Statement, 12 July 2023
- **COVID-19** and **mpox** are no longer considered public health emergencies of international concern, but remain global health threats. WHO has issued standing recommendations for both conditions (COVID-19, mpox).
  For COVID-19, the living guideline for infection prevention and control has also been updated.
- **Ebola** and **Marburg** virus disease outbreaks are expected to continue. WHO has issued an infection prevention and control guideline.
- **Antimicrobial resistance:** Vaccines could avert half a million deaths each year, says a new study published in *BMJ Global Health*.

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CIOMS Secretariat news

Students: Submit your paper for the 2023 CIOMS award

The CIOMS annual award of $1500 US is available to medical students for the best peer-reviewed article published in English on clinical research in one of the following areas:
• Medicines safety and efficacy/effectiveness,
• Pharmacovigilance, or • Research ethics.

Deadline: 31 October 2023

☞**Find more information here.**

Images by Jan Vašek from Pixabay

Patient involvement in the development, regulation and safe use of medicines
(Report of the CIOMS Working Group XI)

Soon to be available in Japanese

医薬品の開発，規制，安全な使用への患者参画
ーCIOMS 作業部会 XI 報告書

The CIOMS Working Group XI report on Patient involvement in the development, regulation and safe use of medicines is soon to be available in Japanese. This will make the guidance accessible for patients and the public in Japan, many of whom are not familiar with English. The translation was prepared by a team at the Japanese Institute for Public Engagement (JI4PE). We thank the team for their excellent work.

A pre-print version has been announced in the Japanese journal *Rinsho Hyoka (Clinical evaluation)* and is due to be published online in September 2023. The print version, with final corrections and minor format changes, will subsequently be posted at the same web address.

☞ **Link to pre-print version** (full text coming soon)

The translation of the CIOMS consensus report can support the development of guidance on patient and public involvement (PPI) in Japan.

Image from: https://ji4pe.tokyo/pdf/2023ji4pe-CIOMS.pdf

World Patient Safety Day 2023 — 17 September 2023

"Elevate the voice of patients!"

For Patient Safety Day, the World Health Organization lit up Geneva's Jet d'Eau in orange, echoing its commitment to **patient and family engagement for safer care**.

The CIOMS Working Group XI report: The "How-To" guide to patient involvement

Find us on the web

https://cioms.ch

1 July– 27 September 2023:

Ongoing CIOMS Working Groups (WG)

Meeting minutes are posted on the groups' webpages:

- Artificial Intelligence in Pharmacovigilance (WG XIV)
- Good Governance Practice for Research Institutions
- Educational standards for health professionals participating in medicines 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
- **NEW Working Group:** Pharmacoepidemiology (WG XV)

25 756 visitors from

>180 countries

16 041 subscribers

Top ten CIOMS publications

Downloads
1 July– 27 September 2023

Living documents		Glossary of ICH terms and definitions	**1538**
		CIOMS Cumulative glossary, with a focus on pharmacovigilance	**532**
Working Group reports			
*	2022	Patient involvement (Working Group XI)	**259**
**	2005	Management of Safety Information from Clinical Trials	**220**
***	2016	International ethical guidelines for health-related research involving humans	**198**
	2010	Practical Aspects of Signal Detection in Pharmacovigilance	**161**
	2020	Drug-Induced Liver Injury (DILI)	**146**
	2021	Clinical research in resource-limited settings	**134**
**	2005	Chinese translation: Management of Safety Information from Clinical Trials	**126**
	1999	Reporting Adverse Drug Reactions: Definitions of Terms and Criteria for Their Use	**115**

* Soon to be available in Japanese, see page 7

** Also available in Chinese

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

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