What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH | December 2022 | **Newsletter** | **# 40**

Quick links

Conferences

2022 CoRE Scientific Conference

Patients as Partners for Health: Co-creating Equitable Access to Health Products and Services

5–6 October 2022, Singapore / hybrid event

Hosted by the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School in Singapore, this two-day event focused on areas of patient engagement for health products access equity and sustainable health systems. Adjunct Professor John Skerritt, Deputy Secretary for Health Products Regulation within the Australian Government Department of Health and Aged Care, and CIOMS Secretary-General Lembit Rägo served as Scientific Chair and Vice Chair of the conference respectively, and five CIOMS Working Group members were among the speakers.

In conjunction with the conference, CoRE and CIOMS signed a Memorandum of Understanding (MoU) to explore opportunities for information exchange and cooperation.

☞ **Conference website**

*(**Below, first row from left**) The CIOMS report on Patient Involvement. — Four Working Group members (➡) were part of the conference's scientific committee. — At the MoU signing ceremony. (**Second row**) Impressions from the conference.*

Conferences (continued)

20th International Conference on Pharmaceutical Medicine (ICPM)

19–21 October 2022, Athens, Greece / hybrid event

CIOMS Secretary-General Lembit Rägo delivered the welcome address from CIOMS, and Executive Committee member Dominique Sprumont spoke about the Principles for good research governance, which are being developed in an ongoing CIOMS Working Group.

☞ **Conference website**

(***Above***) *At the official opening of the 20th ICPM*

IFAPP is a CIOMS member organization. Two recent CIOMS publications featured in the October issue of **IFAPP TODAY**.

6th European Pharmacovigilance Congress (EUPV)

7–8 November 2022 (virtual); 10 November 2022, Milan, Italy

(***Above***) *Among the speakers at the 6th EUPV, from left: Lembit Rägo, Hervé Le Louët, Chia-Yu Qu, Panos Tsintis and Andrew Bates.*

CIOMS was again well represented at the European Pharmacovigilance Congress, with presentations by Working Group members on the following topics:

- Patient involvement in the development, regulation and safe use of medicines;
- Serious cutaneous adverse reactions (SCARs);
- Benefit/risk of medicines; and
- Artificial intelligence in pharmacovigilance.

☞ **Conference website** | **Agenda and speakers**

Fight the Fakes week

5–11 December 2022

This event called for a more secure global medicines supply chain. Secretary-General Lembit Rägo was invited to attend the opening event in Geneva.

☞ **Informational materials**

Also on this topic:

☞ **CIOMS Special Newsletter on Combating substandard and falsified medical products (issued 20 February 2020)**

Dissemination

of CIOMS reports is essential for the recommendations to be widely implemented.

The Working Group XI report on Patient involvement was introduced at several conferences (above) and international meetings (below), and at these events:

- Reuters Pharma Event 2022, 11-13 October 2022, Nice, France
- pvnet Summit; Day 1: 8th November 2022, New York, United States
- Clinical Operations in Oncology Trials Europe, 22-23 November, Zurich, Switzerland

See also:

☞ **CIOMS Online training and Webinars webpages**

☞ **Save the dates for the next two webinars**

Like the CIOMS work? Tell your friends

International meetings

EMA Working Parties meeting

15 November 2022, virtual event

CIOMS was invited by the European Medicines Agency (EMA) to present three recent publications at its Working Parties meeting with patient, consumer and health professional representatives:

- the CIOMS Working Group report on Patient involvement in the development, regulation and safe use of medicines,
- the CIOMS Cumulative Glossary Version 2.0, and
- the Glossary of ICH terms and definitions.

☞ **Meeting webpage (includes presentations)**

ICH Assembly

15–16 November 2022, Incheon (Seoul), South Korea

The International Council for Harmonisation (ICH) Assembly meeting was attended by delegates from 20 member and 36 observer organizations. CIOMS is an ICH observer.

Secretary-General Lembit Rägo presented the CIOMS Glossary of ICH terms and definitions, which was well appreciated by ICH delegates and is now linked from the ICH website. CIOMS will update the glossary as agreed with the ICH Secretariat.

☞ **ICH Press release | Agenda**

Webinars: Save the dates

CIOMS/IFPMA webinar

Regulatory systems and regulations to support clinical trial conduct in Africa

19 January 2023, 13:30-15:00 CET

CIOMS and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) are joining efforts to create a platform for dialogue on clinical research in low- and middle-income countries. This first webinar, focused on Africa, will address how collaboration between stakeholders in the clinical research community can build on each other's expertise, capabilities and capacities and how strengthening clinical research infrastructure can lead to a sustainable ecosystem. Language: English, with interpretation in French and Portuguese.

☞ **Register here | Follow updates for the event here**

☞ **CIOMS report on Clinical trials in resource-limited settings:** https://doi.org/10.56759/cyqe7288

2023 CoRE Webinar Series

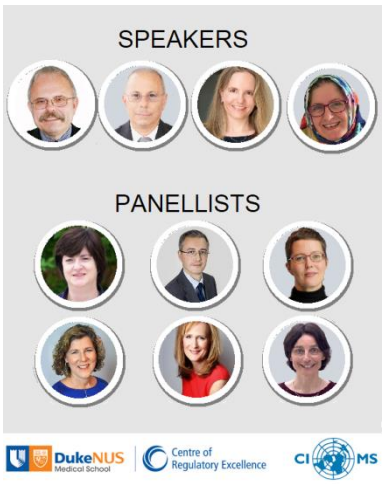
CIOMS Working Group XI Consensus report on Patient involvement in the development, regulation and safe use of medicines

31 January 2023, 11:00-12:10 CET

Patients should be systematically involved throughout a medicine's lifecycle. This webinar brings together patient organization representatives, regulators, and other medicine development experts. Ten members of the CIOMS Working Group XI (**see right**) will introduce the CIOMS consensus report on Patient involvement in the development, regulation and safe use of medicines. The report provides an overview of current knowledge about the benefits of patient involvement and existing initiatives, gives examples and recommendations, and addresses the remaining challenges and practice gaps. It prompts readers to implement its best practice recommendations according to how well they fit with their organizational and national needs.

☞ **Webinar webpage | Register here**

☞ **CIOMS report on Patient involvement:** https://doi.org/10.56759/iiew8982



CIOMS Working Groups

In-person Working Group meetings are back! After two years of travel restrictions, CIOMS Working Group members are getting together again to develop their reports and recommendations.

In-person meetings

3rd Meeting of the CIOMS Working Group on
Education and Training for Health Professionals Participating in Medicines Development
6–7 September 2022, Geneva

2nd Meeting of the CIOMS Working Group on
Artificial Intelligence in Pharmacovigilance
10–11 October 2022, Geneva (hybrid event)

5th Meeting of the CIOMS WG on
Good Governance Practice for Research Institutions
10–12 November 2022, Geneva (hybrid event)

Ongoing CIOMS Working Groups (WGs)	Last WG meeting	
Meeting minutes are available on the groups' websites (links in blue below)		
• Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development	3rd	6-7 Sep 2022
• Working Group XII – Benefit-Risk Balance for Medicinal Products	8th	14 Sep 2022
• Working Group XIV: Artificial Intelligence in Pharmacovigilance	2nd	10-11 Oct 2022
• Good Governance Practice for Research Institutions	5th	10-12 Nov 2022
• Working Group XIII – Real-World Data and Real-World Evidence in Regulatory Decision Making	16th	5 Dec 2022
• MedDRA Labelling Groupings to improve safety communication in product labels	5th	8 Dec 2021
• Severe Cutaneous Adverse Reactions to Drugs – SCARs	8th	12 Dec 2022

Global health issues

Health emergencies

Monkeypox (mpox)

This outbreak continues to meet the criteria for a PHEIC. In its statement of 1 November, the Emergency Committee highlighted reasons for concern: ongoing transmission; global gaps in research, preparedness and response; impact on vulnerable populations; stigma and discrimination; and inequitable access to medical products.

On 28 November, WHO announced that it will use the term 'mpox' (pronounced "em-pox") as a synonym for the old name 'monkeypox', which will be phased out over a period of one year.

Sudan ebolavirus

An outbreak was declared in Uganda in September 2022 and is spreading in the country. There is currently no licensed vaccine against Sudan ebolavirus. In a joint statement, CEPI, Gavi and WHO have outlined a plan to accelerate access to needed vaccines.

A WHO Working Group has recommended three candidate vaccines for inclusion in the planned ring vaccination trial in Uganda: VSV-SUDV (Merck/IAVI), ChAd3-SUDV (Sabin Institute) and biEBOV (Oxford University/Jenner Institute). The trial is led by Uganda's Makerere University and co-sponsored by the Ministry of Health and WHO.

WHO assesses the risk of this outbreak as very high for Uganda, low to high at the regional level, and low at the global level.

COVID-19

The pandemic continues to be a Public Health Emergency of International Concern (PHEIC). In its statement of 18 October 2022, the WHO Emergency Committee made updated recommendations, including on the use of medical products.

Antimicrobial resistance (AMR)

The true dimensions of this silent pandemic have come to light in a recent study. Find an overview in the CIOMS Special Newsletter, issued on 14 November 2022 to support this year's World Antimicrobial Awareness Week.

The CIOMS Special Newsletter on AMR includes some useful visuals (also available in PowerPoint format here).

The latest findings from the GLASS surveillance system suggest that in 2022 common bacterial infections continued to become increasingly resistant to treatments, and that better data are needed to inform effective action by people and communities.

Global preparedness

WHO priority pathogens list to be updated

WHO has launched a global scientific process to update its list of priority pathogens of epidemic and pandemic potential. The list is expected to be published in the first quarter of 2023.

☞ **WHO News, 21 November 2022 | Global R&D Blueprint**

ICMRA framework

The International Coalition of Medicines Regulatory Authorities (ICMRA) has updated this document with experiences and real-life examples from the COVID-19 pandemic. The document was originally published in 2019 as a standard operating procedure.

☞ **ICMRA. Framework for the involvement of health regulatory authorities in the management of global health crises. Version 2 – October 2022**

News roundup

World Health Assembly Resolution WHA75.8
Strengthening clinical trials

The Seventy-fifth World Health Assembly (WHA) has approved a resolution on *Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination*. Resolution WHA75.8 calls on all member states to increase national capabilities to conduct clinical trials in line with international standards for trial design and protection of trial participants. A focus is to be on the health needs in developing countries. The resolution calls for collaboration and coordination, and for greater speed and transparency in conducting and sharing the results of clinical trials during public health emergencies.

☞ **WHO News, 12 September 2022** | **Resolution WHA75.8** (PDF)

▶ WHO Call for Experts: As requested in the resolution, WHO is forming a Technical Advisory Group on Development of Guidance on Best Practices for Clinical Trials. The CIOMS Working Group on Clinical Research in Resource-Limited Settings has been identified as one of the relevant initiatives to take into account.

☞ **WHO Call for Experts** | **CIOMS consensus report on Clinical research in resource-limited settings. 2021.**

Making safe and effective medicines available for children

Many children around the world still do not have access to safe and effective medicines when they need them. The WHO Paediatric Regulatory Network (PRN) supports the availability of quality medical products for children throughout the product lifecycle. It is linked to the Global Accelerator for paediatric formulations (GAP-f), which has recently launched its 2022–2024 business plan.

☞ **WHO Paediatric Regulatory Network (PRN)**

☞ **Global Accelerator for Paediatric Formulations Network (GAP-f)**

IPRP: FAQs on regulatory reliance

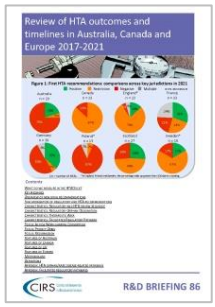
The International Pharmaceutical Regulators Programme (IPRP) has published a collection of frequently asked questions about regulatory reliance.

IPRP is the result of a consolidation that took place in 2018 between the International Generic Drug Regulators Programme (IGDRP) and the International Pharmaceutical Regulators Forum (IPRF). A regulators-only forum, IPRP discusses potential approaches towards regulatory convergence. Once mature, a topic can be handed over to the International Council for Harmonisation (ICH).

☞ **IPRP questions and answers document on Reliance. 30 September 2022**

☞ More on IPRP: **IPRP Overview, June 2022**

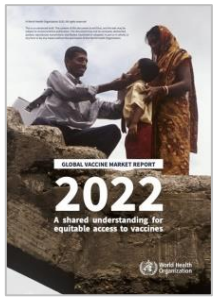
CIRS briefing on HTA outcomes



Health technology assessment aims to determine the relative value of medical products as a basis for decisions on reimbursement. The Centre for Innovation in Regulatory Science (CIRS) has analyzed publicly available data from eight countries on the timing of the first HTA recommendation for new active substances after regulatory approval, as well as the outcome. The findings show considerable differences between countries.

☞ **CIRS R&D Briefing 86: Review of HTA outcomes and timelines in Australia, Canada and Europe 2017–2021.**

WHO Global vaccine market report



WHO has released the first data on the global vaccine market since COVID-19. The report captures lessons from the COVID-19 pandemic and highlights the need for action to expand sustainable access to vaccines for all.

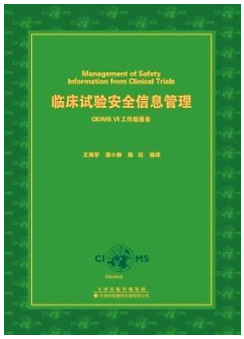
☞ **WHO News release, 9 November 2022**

☞ **Download the report**

CIOMS Secretariat news

Now available: Chinese translation

Management of Safety Information from Clinical Trials
Report of CIOMS Working Group VI



The Chinese translation of the CIOMS Working Group VI report is now available here. This translation will be instrumental in further promoting pharmacovigilance during clinical trials in China in line with international standards.

The translation was produced by the Pharmacovigilance Professional Committee of the Zhejiang Pharmaceutical Association, with extensive input from regulatory and scientific experts. CIOMS thanks the translation and review team for their outstanding collaborative work.

Publishers: Tianjin Science and Technology Translation & Publishing Co Ltd, www.tsttpc.com
To obtain this publication in hard copy, please contact pvinchina@126.com

CIOMS cited

Scientific articles

Al-Imam A, Sami A, Lane S, Younus M. **A concept for causality assessment and causal inference of adverse events cases**. Journal of Biological Research - Bollettino Della Società Italiana Di Biologia Sperimentale. 2 November 2022. https://doi.org/10.4081/jbr.2022.10772

Aronson JK. **When I use a word . . . . Too much healthcare-observational studies**. BMJ. 2022;379:o2734. Published 2022 Nov 11. https://doi.org/10.1136/bmj.o2734

Dal-Ré R, Caplan AL. **The approach to informed consent in acute care research**. Lancet Respir Med. 2022;S2213-2600(22)00408-8. https://doi.org/10.1016/s2213-2600(22)00408-8

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;9:966220. https://doi.org/10.3389/fmed.2022.966220

Labuschaigne M, Mahomed S, Dhai A. **Evolving capacity of children and their best interests in the context of health research in South Africa: An ethico-legal position**. Dev World Bioeth. 2022. https://doi.org/10.1111/dewb.12383

Oehrlein EM, Burcu M, Schoch S, Gressler LE. **Enhancing Patient Centricity of Real-World Data Research: An Exploratory Analysis Using the Patient Experience Mapping Toolbox**. Value Health. 2022;S1098-3015(22)04684-8. https://doi.org/10.1016/j.jval.2022.10.002

Peters U, Turner B, Alvarez D, et al. **Considerations for Embedding Inclusive Research Principles in the Design and Execution of Clinical Trials.** Ther Innov Regul Sci. 2022;1-10. https://doi.org/10.1007/s43441-022-00464-3

Rägo L, Zweygarth M. **The CIOMS consensus report on clinical research in resource-limited settings**. S Afr J Bioethics Law 2022;15(3). In press.

Sewankambo NK, Kutyabami P. **Empowering local research ethics review of antibacterial mass administration research.** Infect Dis Poverty. 2022;11(1):103. https://doi.org/10.1186/s40249-022-01031-6

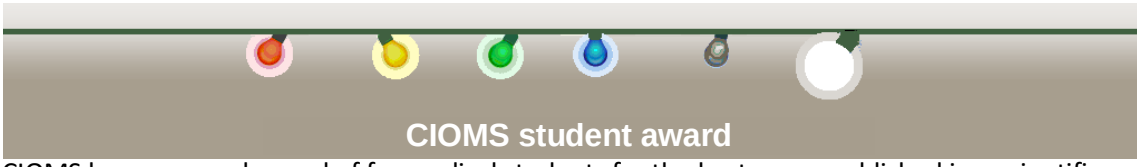
Steel R, Wendler D. **Distinguishing appropriate from inappropriate conditions on research participation**. Bioethics. 2022;10.1111/bioe.13092. https://doi.org/10.1111/bioe.13092

Books

Nguta JM, Belaynehe KM, Arruda AG, et al. **'One Health' Research Ethics in Emergency, Disaster and Zoonotic Disease Outbreaks: A Case Study from Ethiopia**. In: O'Mathúna D, Iphofen R (editors). Ethics, Integrity and Policymaking. Research Ethics Forum, Volume 9. Springer, Cham; 2022: 151-164. https://doi.org/10.1007/978-3-031-15746-2_12

Pan American Health Organization (PAHO). **Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda**. 2022. https://iris.paho.org/handle/10665.2/56139

CIOMS Secretariat news (continued)



CIOMS has an annual award of for medical students for the best paper published in a scientific peer-reviewed journal in English. In 2022, few applications were received by CIOMS and unfortunately none met the standards and criteria required. The Award Committee therefore decided, exceptionally, not to grant the award this year.

For 2023, CIOMS strongly encourages interested students to submit scientific articles published in the areas of clinical research related to medicines safety and efficacy / effectiveness, pharmacovigilance or research ethics.

The award carries a prize of US$ 1500. ☞Find more information here.

Find us on the web

Fourth quarter of 2022 (as of 14 December):

24 928 visitors from

177 countries

8 601 subscribers

Top ten downloads

1	CIOMS Cumulative glossary, version 2.0	1085
2	Glossary of ICH terms and definitions	573
3	Patient involvement (report of Working Group XI)	486
4	(Chinese) Management of Safety Information from Clinical Trials	252
5	International ethical guidelines for health-related research involving humans	200
6	Management of Safety Information from Clinical Trials	200
7	Practical Aspects of Signal Detection in Pharmacovigilance	171
8	(Chinese) Practical Aspects of Signal Detection in pharmacovigilance	161
9	Drug-Induced Liver Injury	149
10	Clinical research in resource-limited settings	126

☞Discover all CIOMS publications

CIOMS Secretariat

Secretary-General
Dr Lembit Rägo
ragol@cioms.ch

Administrative Officer
Ms Sue Le Roux
info@cioms.ch

Technical Writers
Ms Sanna Hill
hills@cioms.ch

Ms Catherine Bates
batesc@cioms.ch

Newsletter editor
Ms Monika Zweygarth
zweygarthm@cioms.ch

Council for International Organizations of Medical Sciences (CIOMS)

Associate partner of UNESCO
In official relations with WHO

1 Route des Morillons
1218 Le Grand-Saconnex
(Geneva), Switzerland
Postal address:
Case postale 2100
CH-1211 Geneva 2

CIOMS is an international non-profit association under Swiss law.
Registration number:
CHE-270.896.260