What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH March 2023 | **Newsletter** **# 41**

Quick links

Past events

CIOMS/GENDRO joint meeting on gender considerations in health research

2 February 2023; Geneva, Switzerland

CIOMS and GENDRO have held a joint meeting on sex and gender considerations in current research ethics guidelines and research ethics committees' work. Participants from academia, research, ethics committees and industry discussed gaps in existing guidance and implementation practices, and proposed ways to advance gender equity in research. The meeting report will be made available on the CIOMS website here.

GENDRO is a not-for-profit, non-governmental organisation with the mission to advance equity through the integration of sex and gender dimensions in research across disciplines.

Women continue to be under-represented in clinical and preclinical research, meaning that their health needs are not adequately studied and addressed.

CIOMS/IFPMA webinar on clinical trials in Africa

19 January 2023, online

Participants at this webinar discussed the importance of evolving and aligning regulatory systems to support clinical trial conduct in line with international regulatory standards.

☞ **Details | Presentations |Recordings:** EN, FR, PT
CIOMS consensus report on Clinical research in resource-limited settings
☞ International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

CIOMS/CoRE webinar on patient involvement

31 January 2023, online

This webinar introduced the CIOMS Working Group report on patient involvement in the development, regulation and safe use of medicines, the first global initiative on patient engagement. Over 700 participants from 83 countries attended the event.

☞ **Details | Presentations | Recording:** YouTube
CIOMS consensus report on Patient involvement
☞ Duke-NUS Centre of Regulatory Excellence (CoRE) Singapore

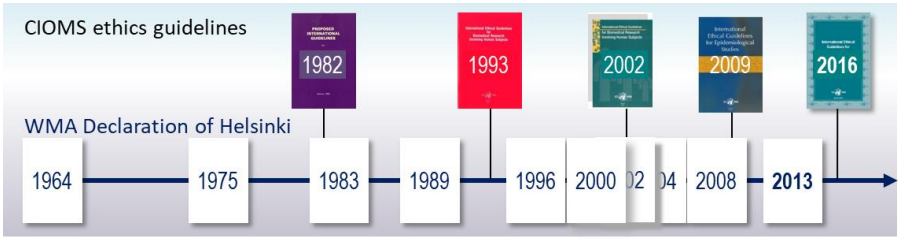
WMA regional expert meeting on the Declaration of Helsinki

24-25 February 2023; São Paulo, Brazil

The World Medical Association (WMA)'s Declaration of Helsinki (DoH) states the ethical principles to be followed in medical research involving human subjects, including research on identifiable human material and data.

The WMA is currently exploring the need for revising the DoH, and is organizing a series of regional expert meetings for this purpose. CIOMS worked closely with WMA to prepare the 2016 CIOMS International ethical guidelines for health-related research involving humans. CIOMS Executive Committee member Dominique Sprumont was invited to speak at the WMA regional expert meeting in Latin America. He gave presentations on two topics: (1) Alignment between the DoH and the CIOMS guidelines, and (2) Ethical considerations for the use of placebo: evidence-based medicine and vulnerability. He described the nature of the CIOMS reports, which are normative as well as educational, and highlighted recent CIOMS reports and ongoing Working Groups that deal with specific aspects of ethical research.

☞ **More about the WMA Declaration of Helsinki**



*(**Above**) CIOMS has a long history of stating ethical principles in medical research in line with the WMA Declaration of Helsinki, together with detailed commentaries on how to apply these principles, including in low- and middle-income countries.*

72nd IFMSA General Assembly

1–7 March 2023; Tallinn, Estonia

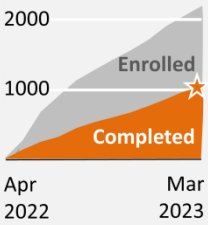
This year's "March Meeting" of the International Federation of Medical Students Associations (IFMSA) was organized around the theme of 'Digital transformation of health systems: towards health for all'. CIOMS Secretary-General Lembit Rägo was invited to speak about responsible research.

IFMSA is a CIOMS member organization. The IFMSA General Assemblies take place in March and in August of each year and are attended by over 800 medical students from over 100 countries.

☞ **IFMSA | March Meeting 2023**

>1000 successful "DILI e-learners"

Within less than a year online, the UMC/CIOMS e-learning course on drug-induced liver injury (DILI) has seen its 1000th participant complete all 8 modules. The course was prepared by experts from the CIOMS DILI Working Group and is based on the CIOMS guideline on Drug-induced liver injury.



ⓘ Now online

Historical CIOMS reports

CIOMS has made available 26 of its previously hard copy-only publications in PDF format. Some of these documents are available online for the first time, for example the CIOMS 1993 *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. These historical reports are of particular interest to researchers and students interested in the development of thinking in bioethics and other related fields, as they include input from pre-eminent experts from around the world, and date back as far as 1979.

*(**Above**) Some of the CIOMS reports newly available online. They cover diverse topics such as: 'Technology transfer: whose responsibility', 'or 'Health manpower out of balance: Conflicts and prospects'.*

☞ **Discover all CIOMS publications**

Conference announcements

ISoP Mid-Year Symposium

1-2 June 2023; Leiden, the Netherlands

This symposium of the International Society of Pharmacovigilance (ISoP) will showcase how the synergy between various scientific disciplines such as epidemiology, (clinical) pharmacology and medical science can improve the quality and impact of monitoring the safe use of drugs. The event will be hosted by the Netherlands pharmaco-vigilance centre Lareb.

- Session 6 on 'The role of patients in pharmacovigilance' will include a presentation about the CIOMS report on patient involvement in the development, regulation and safe use of medicines.

☞ **Conference website | Programme | Registration**

Online searchable programme

DIA 2023 Global Annual Meeting

25-29 June 2023; Boston, United States

This annual event convened by the DIA (founded as the Drug Information Association) will bring together a global community of life sciences professionals, with the aim to create and share knowledge to accelerate healthcare product development.

The programme includes two sessions on the work of CIOMS:

- CIOMS Working Group XII on the Benefit-Risk Balance for Medicinal Products: The CIOMS Working Group XII report (27 June)
- CIOMS: What it Does and the Guideline on Patient Involvement in the Development, Regulation, and Safe Use of Medicines (29 June)

☞ **Meeting website | Registration**

World Congress of Pharmacology 2023

2–7 July 2023; Glasgow, Scotland

This congress will be organized by the International Union of Basic and Clinical Pharmacology (IUPHAR). The event will include a CIOMS workshop on *Guidance for Medicines Safety*, to be held on 5 July, with presentations on:

- Quo vadis CIOMS?
- Patient involvement in drug development and safe use
- Severe cutaneous adverse reactions (SCARs)
- Drug-induced liver injury (DILI)
- Benefit/risk assessment during the life-cycle of medicines

☞ **Conference website | Registration**

Download the programme

Now available:

The 6th European Pharmacovigilance Congress (7–10 November 2022; Milan, Italy)**: Speaker abstracts.** Ther Adv Drug Saf. 2023;14. doi:10.1177/20420986221144584

News roundup

WHO World Health Organization

WHO Executive Board, 152nd session

30 January–7 February 2023; Geneva, Switzerland

The WHO Executive Board discussed more than 30 decisions and resolutions to be proposed to the Seventy-sixth WHO Assembly in May 2023.

Following last year's adoption of WHA Resolution 75/8 on *Strengthening clinical trials*, the Board was informed that available existing guidance, including the CIOMS report on *Clinical research in resource-limited settings*, is being reviewed with a view to develop a WHO guidance document. A draft is expected to be available by the end of 2023. The Board was also informed of the recent guidance adopted by WHO's Expert Committees. These bodies use a global consultative process to develop a comprehensive range of guidelines (**see below**).

☞ **Meeting webpage**

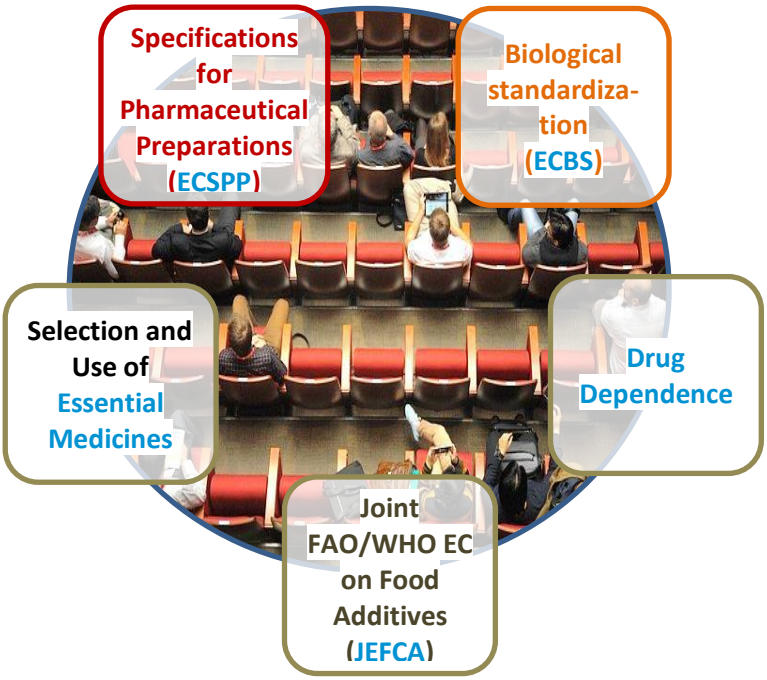
EB152 Meeting documents, including:
Resolutions | Decisions

Preparing for future pandemics

- Governments have begun discussing proposed amendments to the **International Health Regulations (2005) (IHR)**, a legally binding framework that defines countries' rights and obligations in Public Health Emergencies of International Concern (PHEIC) and other acute public health risks.
- At the fourth meeting of the Intergovernmental Negotiating Body, governments have started discussing a "zero draft" of a **new pandemic accord**. The final draft is to be considered by the World Health Assembly in 2024. Researchers have called for independent monitoring of countries' compliance with such an accord.
- A new WHO report analyses the different ways in which COVID–19 has affected **access to medicines** for non-communicable diseases, and proposes a framework for future policy development.

☞ **See also our Health emergency news**

ⓘ Useful resource: The WHO Expert Committees



*(**Above**) The five WHO expert committees that meet regularly. They produce detailed, pragmatic guidelines for regulators and industry globally, published as annexes to the Committees' reports (see right).*

Useful links:

ECSPP

➥Report of 56th meeting (2022).
Eleven annexes, including: (4) Guidelines on technology transfer in pharmaceutical manufacturing, (6) Good practices for R&D facilities, and (7) GMP for investigational products

➥All ECSPP guidelines

➥QA of medicines terminology database

ECBS

➥ Report of 75th Meeting (2022).
Five annexes, including: (3) Evaluation of biosimilars

➥All ECBS-reports– chronological listing

Selection and Use of Essential Medicines:

➥Applications to the 24th meeting, seeking addition, changes and removal of medicines

➥Public comments are invited on the applications. Closing date: 4 April 2023

News roundup (continued)

EMA European Medicines Agency

Human medicines: Highlights 2022

This report gives an overview of the numbers of newly authorised medicines, as well as safety-related regulatory actions for previously authorised medicines in Europe. Safety-related actions include changes to the product information, suspension or withdrawal of a medicine, recall of specific batches and other measures to mitigate risks for patients. The report goes on to provide details on new products that make important contributions to public health, including in recent emergencies; medicines approved for use outside the European Union; early access to medicines addressing public health needs; new medicines for rare diseases; new uses for existing medicines; and notable safety-related regulatory actions taken in 2022.

☞ **EMA News, 16 February 2023**

Boosting the development of children's medicines

The closing report of the EMA and the European Commission (EC) highlights the key improvements achieved by their 2018 action plan to boost the development of medicines for children. The plan has resulted in a stronger focus on unmet medical needs, adapted regulatory processes to support innovation—including a pilot phase of implementing stepwise paediatric investigation plans (PIPs)—and better-aligned data requirements globally.

The action plan had identified ways to address remaining challenges under the 2006 "Paediatric Regulation", notably in certain therapeutic areas (e.g. oncology and neonatology). The EC is currently finalising a proposal to revise the EU's pharmaceutical legislation, including the framework applicable to medicines for children.

☞ **EMA News, 6 February 2023**

EC European Commission

Classifying *in vitro* Diagnostics (IVDs)

The European Union (EU)'s Medical Device Coordination Group (MDCG) has updated its Guidance on classification rules for *in vitro* Diagnostics (IVDs) under Regulation (EU) 2017/746. This revision includes a new Annex 2 with a flowchart to help determine whether or not an IVD is a companion diagnostic, i.e. a device which is essential for the safe and effective use of a corresponding medicinal product.

The MDCG provides advice to the European Commission (EC), and assists the EC and its Member States in applying Regulations (EU) 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices.

☞ See also: **European Commission website. Guidance - MDCG endorsed documents and other guidance** (accessed 23-02-2023)

FDA U.S. Food and Drug Administration

Diversity action plans for clinical trials

Image: Gerd Altmann on Pixabay

Clinical trial participants should represent all people that are likely to use a new medicine being studied.

According to a United States public law signed in December 2022, which incorporates the Diverse and Equitable Participation in Clinical Trials (DEPICT) Act, the FDA is to require diversity action plans for late-stage clinical studies. Waivers are allowed in certain circumstances, for example during public health emergencies, or if a condition is not considered prevalent in the general population.

A Perspective in the *New England Journal of Medicine* has welcomed these new incentives, which can lead to the building of a more sustainable infrastructure for inclusive clinical trials. While the FDA is yet to finalize its draft guidance published in April 2022, companies have been advised to start preparing now for the future legal requirements.

☞ **See also page 1: CIOMS/GENDRO meeting on gender considerations in health research**

Health emergency news

- **Avian influenza A (H5N1):** In February 2023, Cambodia reported its first two human cases since 2014. WHO has called for continued surveillance and provided advice to minimize transmission, even though this virus and other zoonotic influenza viruses have not so far been transmitted easily between humans.

- **Marburg virus disease (MVD):** First-time outbreaks have been confirmed in Equatorial Guinea on 13 February—ongoing at the time of writing— and in Tanzania on 21 March. Currently there are no approved vaccines or antiviral treatments for this highly infectious and often fatal disease. In February WHO convened an urgent meeting of the Marburg virus vaccine consortium (MARVAC). An event-driven efficacy trial design has been proposed.

- **Mpox (monkeypox virus):** The WHO Scientific Advisory Group for the Origins of Novel Patho–gens (SAGO) provided recommendations on studies that should be conducted to better understand the virus.
  Mpox will maintain the PHEIC status noting the persisting transmission in some countries and remaining research gaps.

- **Dengue and chikungunya**, two mosquito-borne arboviral diseases that can have serious public health impacts, have spread beyond the historical areas of transmission in the Americas.

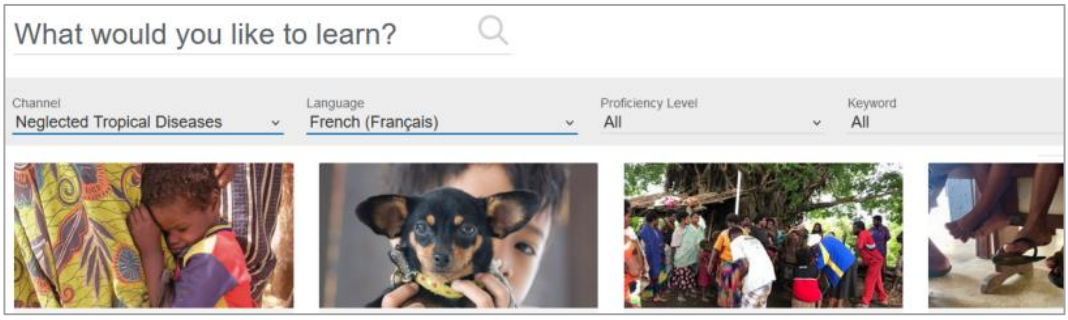
- **COVID–19** remains a public health emergency of international concern (PHEIC). In its statement, the emergency committee has requested WHO to assess the implications for developing and authorizing new products once the PHEIC ends. Countries should continue to monitor variants and to conduct UNITY studies according to the WHO-developed epidemiological protocols.
  In February, WHO experts laid out their decision process on updating COVID-19 vaccines in a *Nature Medicine* commentary.
  In March 2023 WHO updated its tracking system of SARS-CoV-2 variants and working definitions of variants of concern, variants of interest and variants under monitoring, in order to better identify threats emerging in addition to those posed by the current Omicron variants.

- **Sudan ebolavirus:** On 11 January, Uganda declared the end of the outbreak caused by this Ebola virus species, against which no therapeutics and vaccines have been approved yet. WHO has provided an overview of the situation and recommended measures to reduce the risk of Ebola virus transmission.

- **Cholera** has been spreading since mid-2021. The outbreak is compounded by a persisting vaccine shortage. At least 24 countries were affected as at 22 March 2023, with a higher average case-fatality rate than in previous years. WHO assesses the risk at the global level as very high.

ⓘ Useful resource:

The OpenWHO learning platform to improve the response to health emergencies



(Above) *The OpenWHO learning platform offers nearly 200 free self-paced online courses across 65 languages to improve the response to health emergencies. As of February 2023 the platform had 7.5 million total enrolments. It has been chosen as the Learning Platform of the Year at the 2023 Learning Awards in London.*

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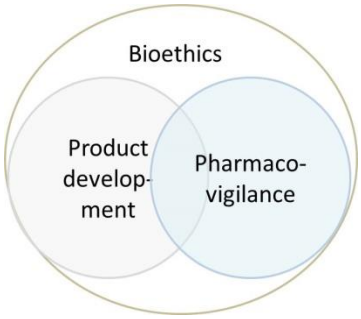
Feature article

Why listening to, and involving patients, is key to successful drug development and management. By CIOMS Working Group XI member Stella Blackburn. Posted in: Medhealth Outlook, MedInsights section.



(***Above***) *The CIOMS areas of work*

Ongoing CIOMS Working Groups

	Recent meetings
• Good Governance Practice for Research Institutions ➥ draft report to be published for comment soon	27 Mar 06 Feb
• Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development	30 Jan
• Working Group XII – Benefit-Risk Balance for Medicinal Products	26 Jan
• Working Group XIII – Real-World Data and Real-World Evidence in Regulatory Decision Making	05 Dec 2022
• Working Group XIV: Artificial Intelligence in Pharmacovigilance	19 Jan
• Severe Cutaneous Adverse Reactions to Drugs – SCARs	14 Mar
• MedDRA Labelling Groupings to improve safety communication in product labels	

CIOMS Secretariat news

New collaboration

World Patients Alliance (WPA)

Following the completion of CIOMS' work on patient involvement in the development, regulation and safe use of medicines, a WPA delegation led by Executive Director Hussain Jafri met with CIOMS Secretary-General Lembit Rägo in Geneva to discuss potential areas of collaboration, including clinical trials and antimicrobial resistance.

WPA also expressed interest in establishing a closer relationship with CIOMS. The option of having WPA as an associate member of CIOMS was discussed.

☞ **World Patients Alliance**

CIOMS Executive Committee

Quarterly call; 15 March 2023

At its first call in 2023, the CIOMS Executive Committee was updated on recent CIOMS activities, progress of ongoing Working Groups, as well as possible new topics and future initiatives.

☞Read more about **CIOMS Governance**

Find us on the web

First quarter of 2023 (as of 26 March):

26 555 visitors from

181 countries

10 961 subscribers

Top downloads

1	Glossary of ICH terms and definitions	**1661**
2	Patient involvement (report of Working Group XI)	**535**
3	CIOMS Cumulative glossary, with a focus on pharmacovigilance	**518**
4	International ethical guidelines for health-related research involving humans	**234**
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☞Discover all CIOMS publications

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