What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

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Quick links

Published for comment

Draft report of CIOMS Working Group XI on Patient Involvement

In the last two decades there has been a dawning recognition of the tremendous value that patients can bring to science and technology in health care. The CIOMS Working Group XI —a diverse collective of patients, patient advocates, regulators, academics and industry representatives—has reached a milestone in its collaborative work. The group is inviting comments on its draft report and best practice recommendations on *Patient involvement in the development, regulation and safe use of medicines*. (Read more…)

(Above) *The CIOMS Working Group XI at its 8th Meeting, held in October 2020.*

(Left) *At the early stage of the group's work, CIOMS held an open meeting to seek input from additional patient representatives around the globe.*

(continued)

We are saddened and concerned by the events in Ukraine.
CIOMS has donated CHF 5000 to the emergency aid fund of the Swiss Red Cross.

See also: WHO updates — Donate (via WHO Foundation)
World Medical Association (WMA) press releases — Medical help fund for Ukraine

Published for comment (continued)

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

People who live with a disease, and those who care for them, have a unique "front line" expertise and perspective of their condition and its treatment. Their views should be taken on board at every step – from the first discovery of a medicine to its retirement from the market.

A great many people and organisations work closely together to make sure that each medicine is fit for purpose. The report of the CIOMS Working Group XI covers a wide range of aspects in 11 chapters:

1 Introduction
2 Landscape
3 Guiding principles
4 Advancing treatments
5 Use of real-world data
6 Product labelling
7 Rapid safety communication
8 Additional risk minimisation
9 Clinical practice guidelines
10 Low- and middle-income countries
11 Pandemic considerations

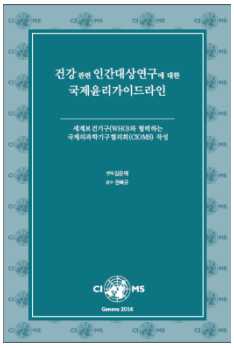
The annexes include a glossary of terms and a collection of case studies of patient involvement.

Views on patients' role in the development, regulation and safe use of medicines are constantly evolving, and they differ enormously across the globe. This report is intended as a pragmatic handbook that proposes good practices, for readers to review and select those which best fit their current organisational needs. It offers a wealth of information for anyone involved in decision-making on medicines.

☞ **The document is open for comment until 11 April 2022.**
Find more information here.

New translation

Korean translation of CIOMS Ethical Guidelines



The Korean translation of the 2016 CIOMS/WHO *International ethical guidelines for health-related research involving humans* is now freely available on the CIOMS website here. We thank the Korean Association of Institutional Review Boards for preparing this translation.

The CIOMS/WHO ethical guidelines are universally acknowledged as a standard in health research. They provide internationally vetted ethical principles and detailed commentary on how these principles should be applied, with particular attention to conducting research in low- and middle-income countries. With this latest translation, the guidelines are now available in ten languages (click to access):

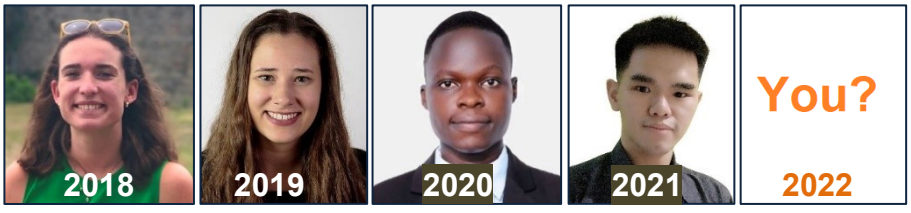
English, French, Spanish, Russian, Arabic, Chinese, Portuguese, Ukrainian, Japanese and Korean.

Announcing:

2022 CIOMS student award

The CIOMS annual award of US$ 1500 for the best scientific article in the areas of pharmacovigilance and research ethics is available to medical students. The article must have been published in a scientific peer-reviewed journal in English. The deadline for submissions is **31 October 2022.**

Past winners:



Read more...

International events

Towards Ethical Guidance to Protect Healthy Volunteers in Biomedical Research

Image from: Meeting website, https://hvworkshop.sciencesconf.org/

Online workshop, held 15-16 February 2022 by the Ethics Committee of the Institut national de la santé et de la recherche médicale, Inserm (the French National Institute of Health and Medical Research)

Initiated by a working group of the Inserm Ethics Committee, this meeting aimed at paving the way towards an international consensus and guidance in biomedical research involving healthy volunteers. It will be followed by remote work in thematic groups. A second in-person workshop will be held once international travel is possible again.

CIOMS Secretary-General was an invited speaker in the concluding session, which dealt with the 4Rs of protecting healthy volunteers: "Respect, Reduce, Refine and Replace". Also among the speakers were the current or former CIOMS Working Group members Aude Le Roux (Sanofi), Dirk Lanzerath (European Network of Research Ethics Associations) and Wei Zhu (Shanghai Ethics Committee for Clinical Research, China).

☞ **https://hvworkshop.sciencesconf.org/**

In brief

At the **28th Session of the UNESCO International Bioethics Committee (IBC)**, CIOMS Working Group member Ames Dhai was elected as IBC Chair for the period 2022-2023. She has previously served as IBC Vice-Chair during the past two years. — Congratulations!

Ames Dhai (centre) is pictured here in October 2019 in Mérida, Spain, at the 5th Meeting of the former CIOMS Working Group on Clinical Research in Resource-Limited Settings.

Now published

Therapeutic Advances in Drug Safety

The 5th European pharmacovigilance congress: speaker abstracts

The 5th European pharmacovigilance congress was held on 1–3 December 2021. More than 20 presentations were given at the congress, including updates from CIOMS and from the International Council for Harmonization (ICH) presented by Lembit Rägo, CIOMS Secretary-General, and updates from the Uppsala Monitoring Centre (UMC) presented by Hervé Le Louët, UMC CEO and CIOMS President, and Christian Rausch from UMC. The abstracts have now been published in the *Therapeutic Advances in Drug Safety* journal.

☞ **doi: 10.1177/20420986211068914**

Conference announcement

ISoP 2022

Verona (Italy)
20–23 September 2022

Online abstract submission for the 21st Annual Meeting of the International Society of Pharmacovigilance (ISoP 2022) is now open. The theme of the conference is *A New Era of Pharmacovigilance: Challenges and Opportunities*. Accepted abstracts will be published in ISoP's official journal, *Drug Safety.*

☞ **ISoP 2022 conference website**

Deadline for submission of abstracts: 13 May 2022

What's new with COVID-19?

- At the WHO-hosted COVID-19 Global Research and Innovation Forum (24-25 February 2022) scientists, regulatory experts, funders, Member States policy makers and other experts discussed the **future of COVID–19 research**. A report was prepared to support the deliberations and will be updated with information gathered during the Forum.
- Different public institutions have started or proposed a wide variety of initiatives to make **access to COVID-19 innovations** more equitable. A review is available on a new website created by the Dutch public benefit organisation Wemos Health Unlimited.
- Tonnes of **extra medical waste** from the COVID-19 response are threatening human and environmental health. A new WHO report calls for safer and more sustainable health care waste management practices.

Variants

WHO's Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE) has discussed real-world data evidence on **Omicron** sublineages BA.1 and BA.2. Both have similar clinical severity, and infection with BA.1 appears to confer some protection against reinfection with BA.2.

Vaccines

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) has reconfirmed the need for updated vaccines to achieve a broad immune response against circulating and emerging variants.

The WHO mRNA technology transfer hub, located in South Africa, has announced technology transfers to six African countries, while five other countries will receive the technology through the WHO global biomanufacturing training hub in the Republic of Korea. These achievements are part of a larger effort to promote local production in low- and middle-income countries.

Treatment

On 3 March, WHO updated its living guideline on COVID-19 therapeutics as follows:

- Recommendation of **baricitinib—**a Janus kinase (JAK) inhibitor—with corticosteroids for patients with severe or critical COVID-19. When both baricitinib and interleukin-6 inhibitors are available, one should be chosen based on cost, availability and clinician experience. If neither of these options is available, two other JAK inhibitors, **ruxolitinib** and **tofacitinib**, can be considered.
- Conditional recommendation of the monoclonal antibody **sotrovimab** in patients with non-severe COVID-19 at the highest risk of hospitalisation.
- Conditional recommendation of **molnupiravir** for patients with non-severe COVID-19 at highest risk of hospitalization. This is the first oral antiviral drug to be included in the guidelines, and safety data are still limited. WHO recommends active monitoring and other risk mitigation strategies.
- Updated advice on **casirivimab-imdevimab,** to be given only for COVID-19 infections caused by variants other than Omicron.

The recommendation for **remdesivir** is undergoing review due to new trial data. Recommendations for **fluvoxamine** and **nirmatrelvir/ritonavir** are in preparation.

WHO living guideline on drugs for COVID–19

Testing

WHO has issued new guidance on COVID-19 self-testing with rapid antigen-detection tests.

Product assessment

WHO has invited expressions of interest for prequalification of COVID-19-related products for procurement by United Nations agencies and other large buyers. To date, six products have been prequalified. The **WHO prequalification list** identifies quality-assured products, whether or not they have been assessed by a stringent regulatory authority (**SRA**).

WHO News, 22 February 2022.

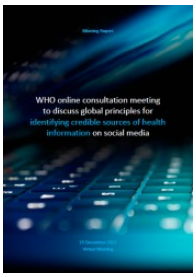
In the longer term, large buyers may choose to rely on assessment by **WHO-listed authorities (WLA),** i.e. those which have reached a reasonable maturity level on the WHO Global Benchmarking Tool. This could motivate countries to invest in regulatory strengthening.

Macé C, Rägo L, Ravinetto R. BMJ Glob Health. 2022 Feb;6(Suppl 3):e008109. doi: 10.1136/bmjgh-2021-008109.

News roundup

New guidance and developments related to the CIOMS areas of work.

WHO World Health Organization



Credible health information on social media

Report of an online consultation held 15 December 2021

Information shared on social media influences health decisions people make on a daily basis. WHO convened an interdisciplinary meeting of experts from around the world to review recommendations from a U.S. National Academy of Medicine discussion paper and see to what extent they can be applied globally to identify credible sources of health information on social media. The meeting report is now available.

WHO Executive Board: 150th session

24–29 January 2022, Geneva / Online

The 150th WHO Executive Board session took place in Geneva in hybrid mode. The members discussed a wide range of challenges facing Member States, and reiterated the need for a strong, accountable, transparent and sustainably financed WHO as the leading authority on global health.

The Board reviewed the collaboration with 71 non-State actors, including CIOMS and some CIOMS member organizations, and decided to renew their status 'in official relations with WHO' for another three years (see also page 7).

☞ **Meeting documents**

ICD-11 comes into effect

11 February 2022

WHO's Eleventh Revision of the International Classification of Diseases (ICD-11) is now officially effective and available online. The ICD is widely used for tracking progress and making decisions on health resource allocation. ICD-11 was first released in 2018 and was adopted at the Seventy-Second World Health Assembly in May 2019.

☞ **WHO News, 11/02/2022**
ICD-11 website

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

Guidance on patient involvement

The U.S. FDA has finalized Part 2 of its series of four guidance documents on Patient-Focused Drug Development, titled *Methods To Identify What Is Important to Patients*. Part 1, on methods of *Collecting Comprehensive and Representative Input*, was finalized in June 2020.

☞ **FDA Patient-Focused Drug Development Guidance Series: website**

EMA European Medicines Agency

New GVP Addendum published for comment

EMA has launched a public consultation on its new Addendum III to Module XVI of the good pharmacovigilance practices (GVP). The draft addendum is titled *Pregnancy prevention programmes and other pregnancy-specific risk minimisation measures*. It defines the elements of a pregnancy prevention programme and provides criteria for deciding when such a programme or other risk minimisation measures are appropriate to avoid adverse pregnancy outcomes due to use of medicines and to preserve health of both the mother and the child.

☞ **Draft Module XVI Addendum III**
Please submit comments via the EU survey tool.
Closing date for comments: 31 May 2022

EMA news in brief

- Since 31 January 2022, sponsors wishing to run a trial in several European countries can submit a single application via the Clinical Trials Information System (CTIS), in line with the EU Clinical Trials Regulation.
- EMA has started setting up a coordination centre for the Data Analysis and Real World Interrogation Network (**DARWIN EU**), which is to deliver evidence from real-world healthcare data sources across the European Union.

CIOMS cited

Scientific articles

Ángeles-Llerenas A, Thrasher JF, Domínguez-Esponda R, López-Ridaura R, Macklin R. **Operation of research ethics committees in Colombia, Costa Rica, Guatemala, and Mexico: Mesoamerican Project**. Salud Publica Mex. 2021.

Burns L, Roux NL, Kalesnik-Orszulak R, *et al*. **Real-World Evidence for Regulatory Decision-Making: Guidance From Around the World**. Clin Ther. 2022 Feb 15:S0149-2918(22)00017-0. doi: 10.1016/j.clinthera.2022.01.012.

Atuire CA, Salas SP, Wright K, *et al*. **COVID-19 vaccine trials with children: ethics pointers.** BMJ Glob Health. 2022 Jan;7(1):e007466. doi: 10.1136/bmjgh-2021-007466.

Berner-Rodoreda A, McMahon S, Eyal N, *et al.* **Consent Requirements for Testing Health Policies: An Intercontinental Comparison of Expert Opinions.** Journal of Empirical Research on Human Research Ethics. 2022 February 10. Online ahead of print. doi: 10.1177/15562646221076764.

Hayashi PH, Lucena MI, Fontana RJ, *et al*. **A Revised Electronic Version of RUCAM for the Diagnosis of Drug Induced Liver Injury**. Hepatology. 2022 Jan 11. doi: 10.1002/hep.32327. Online ahead of print.

Kislovskiy Y, Chappell C, Flaherty E, et al. **Motives and risk perceptions of participants in a phase 1 trial for Hepatitis C Virus investigational therapy in pregnancy**. Research Ethics. December 2021. doi:10.1177/17470161211066159.

Nunes DRdCMA, Monteiro CSdJ, dos Santos JL. **Herb-Induced Liver Injury—A Challenging Diagnosis**. Healthcare. 2022; 10(2):278. doi:10.3390/healthcare10020278.

Roa TM, Biller-Andorno N. **Financial incentives for participants in health research: when are they ethical?** Swiss Med Wkly. 2022;152:w30166. doi:10.4414/SMW.2022.w30166.

Singh JA, Kochhar S, Wolff J, *et al*. **WHO guidance on COVID-19 vaccine trial designs in the context of authorized COVID-19 vaccines and expanding global access: Ethical considerations**. Vaccine. 2022 Feb 28:S0264-410X(22)00175-X. doi: 10.1016/j.vaccine.2022.02.038.

Smith MY, Frise S, Feron J, Marshall R. **Improving the Safety of Medicines via Digital Technology: An Assessment of the Scope and Quality of Risk Minimization Websites in the United States and United Kingdom**. Drug Saf. 2022 Mar 5. doi: 10.1007/s40264-022-01165-4.

Varadan S, Sirinam S, Limkittikul K, Cheah PY. (2022). **The proxy dilemma: Informed consent in paediatric clinical research – a case study of Thailand.** Developing World Bioethics, 1– 10. doi: 10.1111/dewb.12341.

Wan Z, Hazel JW, Clayton EW, *et al*. **Sociotechnical safeguards for genomic data privacy**. Nat Rev Genet. 2022 Mar 4:1–17. doi: 10.1038/s41576-022-00455-y.

White M, Whittaker RG. **Post-Trial Considerations for an Early Phase Optogenetic Trial in the Human Brain.** Open Access Journal of Clinical Trials. 2022;14:1-9. doi: 10.2147/OAJCT.S345482.

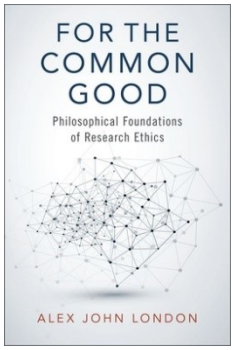
Books

World Health Organization. (2021). **Ethical considerations in research on female genital mutilation.** Available at: https://apps.who.int/iris/handle/10665/350884. License: CC BY-NC-SA 3.0 IGO.

For the common good

Connecting research to the goals of a just social order, the author of this book argues that the array of stakeholders is much wider than typically discussed in research ethics. He proposes a new vision for the philosophical foundations of research ethics, which considers issues of neglect and injustice as well as the various threats to participants' interests.

☞ **London AJ. For the Common Good. Philosophical Foundations of Research Ethics. Oxford University Press. 2022. Freely available at Oxford Scholarship Online, and as PDF.**



The CIOMS ethical guidelines are discussed in several chapters.

News from the CIOMS Secretariat

CIOMS in official relations with WHO

We are delighted to announce that the WHO Executive Board, at its 150th session, decided to maintain the Organization's official relations with CIOMS and commended its continuing contribution to the work of WHO.

WHO reviews its official relationships every three years according to a demanding framework, which was re-designed in 2016 to manage the engagement of an increasing number of players in a complex global health landscape. Currently, WHO is in official relations with 220 non-state actors, among them five international CIOMS members (IFOS, IUPHAR, MWIA, WASPaLM and WMA) and four associate CIOMS members (IFCC, IFMSA, WFC and WONCA).

(Below, top) *The World Health Assembly in the 1950s, in the early years of the existence of CIOMS.*
(Middle) *CIOMS has been in official relations with WHO ever since it was established in 1949 by the Second World Health Assembly in Resolution WHA2.5.*
(Bottom) *In 1952, the Fifth World Health Assembly debated the funding and scope of activities of CIOMS, and noted its new name in Resolution WHA 5.34.*

Image from: *The First Ten Years of the World Health Organization*. WHO; 1958.

WHA2.5. Co-ordination of International Congresses of Medical Sciences : Proposed Collaboration with the Permanent Council

The Second World Health Assembly

1. APPROVES the principles laid down by the Executive Board for collaboration of the World Health Organization with the Permanent Council for the Co-ordination of International Congresses of Medical Sciences, i.e. :

(1) that the Council be recognized as a non-governmental organization to be brought into official relationship with the World Health Organization ;

WHA5.34 Co-operation with the Council for the Co-ordination of International Congresses of Medical Sciences

The Fifth World Health Assembly

1. NOTES that the Assembly of the Council for the Co-ordination of International Congresses of Medical Sciences has modified the title of the Council to " Council for International Organizations of Medical Sciences " (CIOMS) ; and

2. ENDORSES resolution EB9.R14, adopted by the Executive Board at its ninth session, concerning the principles for co-operation with the Council.[28]

New CIOMS Executive Committee member

CIOMS welcomes **Cordula Landgraf** to its Executive Committee. Cordula is the Director of Communications & Stakeholder Engagement at the Swiss Clinical Trial Organisation (SCTO). She will represent the International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine (IFAPP) in the CIOMS Executive Committee, replacing Gustavo Kesselring, who is no longer a member of the IFAPP Board of Officers.

We thank Gustavo for his past commitment, and IFAPP for Cordula's nomination. Pending the approval of her membership by the CIOMS Assembly at its May meeting, Cordula will participate in the Executive Committee as an observer.

CIOMS topic areas and Working Groups (WG)

Meeting minutes are published on the Working Groups' webpages (click on group names below).

	Working Group	Started
Ethics	**Good governance practice for research institutions**	July 2021
Product develop-ment	**Educational standards**	April 2021
	Patient involvement (WG XI) Report posted for comment (see page 1)	April 2018
	MedDRA labelling groupings	April 2019
Pharmaco-vigilance	**Benefit-risk balance for medicinal products (WG XII)**	September 2019
	Real-world data and real-world evidence in regulatory decision-making (WG XIII)	March 2020
	Severe cutaneous adverse reactions (SCARs)	February 2021

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As at 23 March
☐ = Up to 22 March inclusive

1 January – 22 March 2022

Total visitors: 24 627

Top 3 countries

1	United States	6 941
2	China	2 515
3	India	2 402

Top 3 downloads

1	CIOMS I form	2 101
2	Cumulative pharmacovigilance glossary Version 1.1	367
3	CIOMS 2016 Ethical Guidelines	337

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