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International events

International conference on China's Ethics Committee Development (ECD 2021)

2 December 2021, Shanghai, China / online

For the third year running, CIOMS has collaborated with the Shanghai Clinical Research Council (SCRC) and the Shanghai Ethics Committee for Clinical Research (SECCR) to organize a conference on issues of ethics and clinical research. This year's focus was on the ethical, legal and social issues in

the use of "big data" and biobanks in health research. The event attracted over 650 participants from law schools, legal firms, medical institutions, hospitals, public health, and ethics committees, mostly in China, Europe and Australia.



(Left, top row from left) Conference speakers **Guangjun Yu**, **Rui Ding**, **Duoqi Xu**, **Yuan He**, **Chingli Hu**, **Wei Zhu**, **Renzong Qiu**, **Xiaomei Zhai**, **Kun Qian**, **Ruipeng Lei**. (Bottom row, from left) **Menno Mostert***, **Frédéric Erard**, **Dominique Sprumont***, **Lembit Rõgo***, **Christian Dierks**, **David Townend***, **Mark Taylor**, **Dirk Lanzerath**. **=CIOMS speaker*

(Right, top row) Session chairs **Qi Lu** and **Rong Wu**; (middle row) **Yiqun Xi** and **Yanling He** and (bottom row) **Wei Zhu**, smiling at a greeting from the SECCR Chairman, **Chingli Hu**.

Full name of the event: Conference on the Ethical, Legal and Social Issues (ELSI) in the Use of Big Data & International Conference on China's Ethics Committee Development (ECD 2021).

Links to recordings will be made available on the [CIOMS Conferences webpage](#)

Read more about previous SCRC / CIOMS / SECCR events: [Launch of Chinese translation of CIOMS 2016 Ethical Guidelines](#) (27 April 2019) | [ECD 2019](#) (8 December 2019), [ECD 2020](#) (20 November 2020)

International events (continued)

ICH Assembly

“Vancouver” Virtual Meeting, 17–18 November 2021

At its 43rd Assembly meeting, ICH welcomed the regulatory authority of Mexico as a new member, and those of Egypt, Indonesia and Ukraine as observers. Updates were presented on existing and future harmonization activities, and priorities for the selection of new topics.

CIOMS is an ICH observer since 2016, and was represented at the Assembly meeting by its Secretary-General, Lembit Rägo.

 [ICH Press release, 25 November 2021](#)

More about ICH: *The International Council for Harmonisation (ICH) is the world’s oldest and largest pharmaceutical harmonization initiative. The ICH 30th Anniversary Publication outlines ICH’s history and current work, as well as the views of stakeholders, including CIOMS, on the impact and future of ICH.*



World Health Assembly (WHA) 2nd Special Session

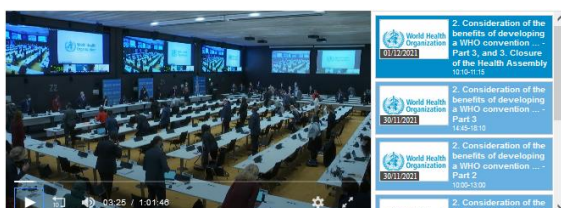
29 November – 1 December 2021, online

WHO member states have gathered for the second special WHA session* in history, and [adopted a decision](#) to work together to establish an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response.

CIOMS was included on the [list of participants](#) as a non-state actor in official relations with WHO, and was represented by its Secretary-General, Lembit Rägo.

**The first special WHA session was convened in 2006 after the death of WHO Director-General Dr Lee Jong-wook to accelerate the election of the next Director-General.*

 [Event webpage](#)
(includes links to documents and webcasts)



Brazil rare diseases conference

24–25 September 2021, São Paulo / online



The 6th Edition of the conference on the **Scenario of Rare Diseases in Brazil** attracted more than 700 online registrations and around 200 people in person. CIOMS Secretary-General Lembit Rägo participated in a Round Table discussion on *Clinical Research: Participation of Patients and Families in the Approval and Registration of Medications*.

 [Conference website](#)

ISoP 2021

8–10 November 2021, Oman/online



The 20th Annual Meeting of the International Society of Pharmacovigilance (ISoP) was held in a hybrid format: The main scientific programme was offered on-line, with additional on-site activities taking place in Muscat. The theme of ISoP 2021 was “Integrated Pharmacovigilance for Safer Patients”: how can different activities and stakeholders in pharmacovigilance be brought together, creating more effective systems? CIOMS Secretary-General Lembit Rägo gave the traditional CIOMS lecture, titled *Results from CIOMS Working Group XI on patient involvement in the development and safe use of medicines*.

 [Conference website](#)

European Pharmacovigilance Congress

1–3 December 2021, online



CIOMS was prominently represented at the 5th European Pharmacovigilance Congress. CIOMS President Hervé Le Louët chaired the sessions on updates from international pharmacovigilance organizations and on COVID-19 vaccine pharmacovigilance. The CIOMS Secretary General presented updates from CIOMS and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

 [Conference website](#)

International events (continued): Focus on Africa

SCoMRA V and AMRC VII

22–26 November 2021, virtual conference

Held under the auspices of NEPAD's African Union Development Agency (AUDA), the **5th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA V)** and the **African Medicines Regulators Conference (AMRC VII)** brought together participants from African and global organizations. Delegates discussed the regulatory strengthening and harmonization efforts in Africa and how they facilitate medical product research, development and manufacturing to bring needed medical products to patients.



In his keynote address on Clinical trials: Current Status and Future Vision, *CIOMS Secretary-General Lembit Rägo* emphasized the urgent need for more good quality clinical trials in Africa and pointed to useful guidance, including relevant *CIOMS Working Group reports*.



(Left) Challenges and solutions faced in conducting clinical research in low-resource settings were illustrated impressively by Professor E N'Goran from Côte d'Ivoire at a webinar of the *Pediatric Praziquantel Consortium* held on 8 December 2021. The event was moderated by Bert Leufkens, Chair of the *CIOMS Working Group on Clinical Research in Resource-Limited Settings*. Find the [webinar recording here](#).

Related news

African Medicines Agency (AMA) to go ahead

Following the ratification by the requisite 15 countries (shown in green in the infographic to the right), the [Treaty](#) for the Establishment of the African Medicines Agency (AMA) entered into force on 5 November 2021.



Similarly to the European Medicines Agency (EMA), the AMA is organized as a network of national regulatory authorities. As a first step towards establishing and

operationalizing the AMA, the African Union Commission is currently evaluating expressions of interest from member states to host the AMA headquarters.

[AMA Press release, 9 November 2021](#)

Image source:
[AMA Treaty Infographic](#)
(as at 5/11/2021)

During the inaugural "Conversation", hosted on 15 November 2021 by the Centre of Regulatory Excellence (CoRE) of the Duke NUS Medical School in Singapore, the Executive Director of the European Medicines Agency, Emer Cooke, confirmed her agency's readiness to support the AMA as it is set to take up operations as a network of regulatory authorities.

[Missed it? Watch the video here.](#)

Conference announcement

International workshop

"Towards Ethical Guidance to Protect Healthy Volunteers in Biomedical Research"

Organized by the French national research institute, Inserm

15–16 February 2022, Paris, France / onsite & online

This workshop will be quite unique in that it will include viewpoints from a variety of research fields that involve healthy volunteers, and it will be attended by experts from multiple geographic regions. It is expected that this "landscaping exercise" will be a first step towards recommendations on best practices to protect these vulnerable research participants around the globe.

Organisations that support the workshop include [UNESCO](#), [EDCTP](#), [EUREC](#), [ANRS](#), [Espace éthique de réflexion Ile-de-France](#), [The Conversation](#), [DNDi](#) and [CIOMS](#). Dr Lembit Rägo, CIOMS Secretary General, will speak on the perspective of future guidelines to protect healthy volunteers globally.

[More information: hvworkshop.disc@inserm.fr](#)

What's new with COVID-19?

- At its Ninth Meeting on 22 October 2021, the [COVID-19 Emergency Committee](#) convened by WHO agreed that the pandemic remains a **public health emergency of international concern**.
- WHO has established a new Scientific Advisory Group for the Origins on Novel Pathogens (“[SAGO](#)”) to advise the WHO Secretariat on technical and scientific considerations regarding emerging and re-emerging pathogens.
- WHO and the Global Fund have [warned](#) that **inequalities will block progress towards ending AIDS, tuberculosis and malaria, as shown in their new report**.
- At the second-ever Special WHA session (see also page 2) WHO member states adopted a sole consensus [decision](#), titled “The World Together”, to develop a **historic global accord on pandemic prevention, preparedness and response**.
- The Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE), the United Nations Environment Programme (UNEP) and WHO are working together to better prevent, predict, detect and respond to global health threats. They have agreed on a [common definition of the “One health” approach](#).

Variants



On 26 November 2021, WHO [designated](#) the variant B.1.1.529 a variant of concern, named **Omicron**. Studies are under way to understand the impact of this variant on transmissibility, severity of infection, performance of vaccines and diagnostic tests, and effectiveness of treatments. A [technical brief](#) for countries to enhance readiness for Omicron was issued on 10 December 2021.

Vaccines



- WHO has issued an [interim statement](#) advising member states to consider the direct and indirect benefits of **immunising children and adolescents** against COVID-19. However, as long as many parts of the world are facing extreme vaccine shortages, countries with high coverage in their high-risk populations should prioritize global sharing of COVID-19 vaccines through the COVAX facility before vaccinating children and adolescents, who are at low risk for severe disease.
- WHO has issued [interim recommendations](#) (updated 9 December) on the use of the **Janssen Ad26.COV2.S** vaccine. In brief, using only one dose may have advantages in some circumstances, and countries may consider using another approved vaccine for the second dose and/or increasing the interval between doses.

Treatment



- Emergency use approval for **molnupiravir** has been granted in the UK, and has been recommended to the U.S. FDA by an advisory committee. Molnupiravir is an oral ribonucleoside analogue to treat mild-to-moderate COVID-19 in adults at risk for progressing to severe COVID-19 and/or hospitalization.

- The Medicines Patent Pool (**MPP**) and Merck Sharp & Dohme (MSD) have entered into a [licence agreement](#) to increase future access to molnupiravir in low- and middle-income countries.
- MPP has also [announced](#) the signing of a voluntary license agreement for Pfizer's experimental COVID-19 oral antiviral treatment combination **PF-07321332** and low-dose ritonavir, which [was found to](#) reduce the risk of hospitalization or death by 89% in a Phase 2/3 study.
- WHO has updated its [living guideline on the clinical management of COVID-19 patients](#) to include a new chapter on the management of **multisystem inflammatory syndrome in children**, a rare but serious condition requiring specialized care, and sometimes intensive care.
- In its [living guideline on therapeutics and COVID-19](#), WHO has advised against the use of convalescent plasma.

Regulation



The International Coalition of Medicines Regulatory Authorities (**ICMRA**) has issued:

- a [statement](#) on the need for continued focus on COVID-19 therapeutics (10 December 2021); and
- a [reflection paper](#) on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 pandemic (10 December 2021).

ICMRA and WHO have jointly published:

- A report [on regulatory flexibilities](#) implemented by national regulatory authorities during the pandemic (3 December 2021); and
- An [Emergency Use Approval deep dive report](#) on the review of provisions and procedures for emergency authorisation of medical products for COVID-19 among ICMRA members (10 December 2021).

News roundup

New guidance documents and reports related to the CIOMS areas of work.

ICH

ICH E8(R1) Guideline on clinical studies

ICH has adopted its revised [General considerations for clinical studies; E8\(R1\)](#). The revision proposed to: (1) identify a basic set of critical-to-quality factors that can be adapted to different types of trials; (2) address a broader range of trial designs and data sources; and (3) cross-reference all other ICH Guidelines that should be referred to when planning clinical studies.

The ICH E8 revision is part of the Good Clinical Practice (GCP) renovation process. ICH E6 is also under revision. In April 2021, ICH shared the [E6\(R3\) Draft Principles](#) to facilitate transparency and common understanding.

The ICH GCP guidelines and their renovation were considered by the former CIOMS Working Group on Clinical research in resource-limited settings.

U.S. FDA

Draft guidance on benefit-risk assessment

The U.S. Food and Drug Administration (FDA) has [invited comments](#) on its [draft guidance on Benefit-Risk Assessment for New Drug and Biological Products](#). The comment period ended on 29 November, but according to Federal Regulations, comments can be submitted any time.

This draft guidance is of key interest for the [CIOMS Working Group XII](#), and has also been considered by the [CIOMS Working Group XI on Patient involvement](#).

Guidance on real-world evidence

Up-to-date information about the status of U.S. FDA activities around the development and use of real-world data and real-world evidence can be found [here](#). Two guidance documents are open for comment:

- [Considerations](#) for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products
- [Real-World Data](#): Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

This U.S. FDA guidance is being considered by the [CIOMS Working Group XIII](#).

WHO

Updated Essential Medicines Lists (EML)

WHO has published its new model lists of essential medicines: the [22nd list for adults](#) and the [8th list for children](#). New medicines, indications and formulations have been added, including for various cancers, diabetes and infectious diseases. The Committee also endorsed updates to the Access, Watch and Reserve ([AWaRe](#)) [classification of antibiotics](#) and considered various other reviews. It underscored the urgent need for a range of actions to ensure equitable and affordable access to essential medicines.

[Executive summary of the WHO Expert Committee's report](#)



Antimicrobial resistance

Draft WHO EML Antibiotic Book

Antimicrobial resistance remains a significant and growing challenge for public health globally. WHO has launched a public consultation for its EML Antibiotic Book, which aims to improve antibiotic prescribing globally in line with the Essential Medicines Lists and the AWaRe classification.

[Draft for comment](#)

Deadline for comments: 31 January 2022

HIV drug resistance report

Minimizing the spread of HIV drug resistance is a critical aspect of the broader global response to antimicrobial resistance. The findings of a new [WHO report](#) emphasize the need for more viral load testing, better adherence counselling, and prompt switching of regimens in individuals with treatment failure.

Antimicrobial resistance is an ongoing threat that needs to be addressed in medicines development and use.

2021 CIOMS student award

The 2021 CIOMS award of US\$ 1500 for the best scientific article published by a student in the areas of pharmacovigilance or research ethics goes to **Gilbert Lazarus** for his paper:

Lazarus G, Tjoa K, Iskandar AWB, et al. **The effect of human immunodeficiency virus infection on adverse events during treatment of drug-resistant tuberculosis: A systematic review and meta-analysis.** PLoS One. 2021 Mar 4;16(3):e0248017. doi: 10.1371/journal.pone.0248017.

Gilbert is a fifth-year undergraduate medical student at the Faculty of Medicine of the Universitas Indonesia. He is aspiring to become a physician-scientist in the field of internal medicine. His research focus revolves around epidemiology and evidence-based medicine, with special interests in the areas of cancer immunology and treatment, COVID-19 and tropical infectious diseases, and metabolic syndrome. He has authored and co-authored more than a dozen peer-reviewed journal articles, has himself peer-reviewed publications for several international journals, and has served as editor-in-chief for the Journal of Asian Medical Students' Association (JAMSA).



Gilbert's ambition is to alleviate the devastating burden of communicable and non-communicable diseases in developing regions. During the COVID pandemic, he and his colleagues launched a nationwide research project to explore the potential involvement of medical student volunteers in Indonesia to help mitigate the crisis.

👉 [Applications for the 2022 CIOMS award are welcome. Read more...](#)

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Scientific articles

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Newsletter article

Zenhäusern G, Jaggi L. **Involving patients and consumers in Swissmedic's regulatory processes: From information sharing to participation.** Swiss Clinical Trial Organization, Regulatory Affairs (RA) Platform. RA Watch No. 6, 28 October 2021. ([Article](#) | [entire newsletter issue](#) – [PDF](#))

Books

Global vaccine safety blueprint 2.0 (GVS2.0) 2021-2023. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. [WHO Institutional Repository for Information-Sharing](#)

Quantitative drug safety and benefit/risk assessment. First Edition. Boca Raton, U.S.:Chapman and Lee/CRC. 2021. ([webpage](#)). Contributors include former CIOMS Working Group members Brian Edwards and Cheryl Renz.

WHO guidance on research methods for health emergency and disaster risk management. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. [WHO Institutional Repository for Information-Sharing](#)

News from the CIOMS Secretariat

UNESCO partnership status renewed

We are delighted that the UNESCO Executive Board has decided to renew the associate status of CIOMS for another eight years until 2029.

CIOMS has been a UNESCO partner since 1961. As a **non-governmental organization in official partnership with UNESCO (associate status)** CIOMS cooperates in defining and implementing UNESCO's programme.

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS)

Evaluation of the cooperation:

Represents the biomedical scientific community through its member organizations. CIOMS is a longstanding and important partner of UNESCO in the field of bioethics and medical sciences.

It has been a strong partner of the International Bioethics Committee (IBC), by providing and exchanging expertise and qualitative data, and by disseminating information regarding UNESCO's work – including IBC reports – in its own research. CIOMS produced the Ethical Guidelines for Health-related research involving humans as the outcome of a meeting it held at UNESCO headquarters in 2015. This document was published in 2016 in all UN languages. Since then, UNESCO has been using these Guidelines in its Assisting Bioethics Committees - ABC Training Programme for the new bioethics committees.



(Above) The CIOMS individual fact sheet as a UNESCO associate partner. From: UNESCO document [212 EX/36 INF](#).

CIOMS Executive Committee meeting

3 November 2021 (online)



The CIOMS **Executive Committee** heard updates on the seven ongoing CIOMS Working Groups, recent outreach activities and publications, planned website improvements, and a number of administrative matters.

Despite the ongoing COVID-19 restrictions, work at CIOMS is progressing. The Executive Committee members commended the CIOMS Secretariat team for supporting the Working Groups effectively in developing their reports on several very timely topics (see below).

CIOMS topic areas and Working Groups (WG)

Legend:

- Patient involvement (WG XI)
- Benefit-risk balance for medicinal products (WG XII)
- Real-world data and real-world evidence in regulatory decision-making (WG XIII)
- MedDRA labelling groupings
- Severe cutaneous adverse reactions (SCARs)
- Educational standards
- Principles of good governance for research institutions

(Background) The SCARs Working Group at its 4th Meeting, held on 7 October 2021

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

Find us on the web



As at 13 December
 □ = Extrapolated to 31 December

Total visitors, 2021 to date: **96 622**

Top 3 countries:

1	United States	22 968
2	India	12 012
3	China	8 974

Total downloads, 2021 to date: **34 289**

Top 3 downloads:

1	CIOMS I form	9 389
2	Cumulative pharmacovigilance glossary*	3 207
3	CIOMS 2016 Ethical Guidelines	2,328

*=Including Versions 1.0 (March 2021) and 1.1 (June 2021)

CIOMS
 Council for International Organizations of Medical Sciences

Season's Greetings from CIOMS and Best Wishes for a Successful 2022!

Dr Lembit Rägo *Prof Hervé Le Louët*
 Secretary-General President

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Thank you for your support in 2021!

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