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New CIOMS Working Group



Working Group XIV – Artificial intelligence in pharmacovigilance

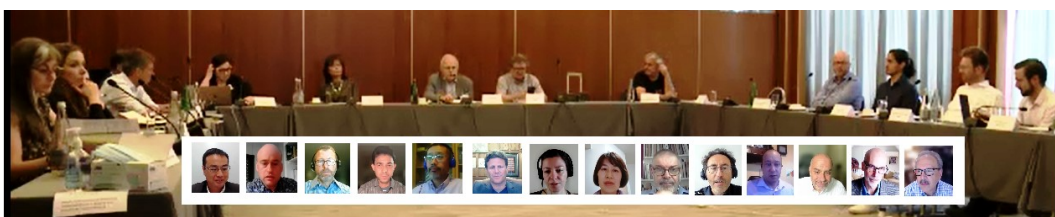
First meeting: 18-19 May 2022, Chavannes-de-Bogis near Geneva (hybrid meeting)

This new CIOMS Working Group aims to establish and promote principles and guidance for the use of artificial intelligence or intelligence augmentation specifically within the field of pharmacovigilance.

Building on the broader initiatives under way, the Working Group will provide practical guidance for

drug developers, regulators, academics, healthcare and service providers. At its first meeting the group listened to the views of different stakeholders, analysed the [concept note](#), and agreed on a realistic set of topics and work methods.

[Working Group webpage](#)



(Above) The CIOMS Working Group XIV at its first meeting, which was held in a hybrid format.

Health emergency news

For almost two years this page has brought you news about COVID-19. As we are learning to live with the pandemic, new emergencies are making headline news. Some of them are highlighted below. International organizations are joining forces to address the underlying causes of global health risks.

- A framework for [One Health cooperation](#) has been agreed by the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) and WHO to tackle the challenges at the human, animal, plant and ecosystem interface, including antimicrobial resistance.
- Investments for health, climate change, pandemic preparedness, digital transformation, food systems, equitable health systems and world peace will be the main topics at the eighth [World Health Summit 2022](#) to be held on 16–18 October 2022, the first that will be held jointly with WHO.



Health emergencies can threaten global health security. Health is a driving force for all sustainable development goals, and it is linked to virtually all sectors of our economies.

Image based on a design by Gerd Altmann from Pixabay

COVID-19

Continuing public health emergency

The WHO Emergency Committee regarding COVID-19 has determined that the pandemic continues to be a public health emergency of international concern (PHEIC), and has updated its recommendations.

🌿 [Emergency Committee statement, 11 April 2022](#)

Treatment

WHO strongly recommends nirmatrelvir/ritonavir for patients with non-severe COVID-19 who are at highest risk of hospitalisation, and called for equitable access to this drug. Updated recommendations were also provided for remdesivir.

🌿 [Living WHO guideline on drugs for COVID-19](#)

🌿 [WHO statement on access to nirmatrelvir/ritonavir](#)

Vaccines

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) has released an interim statement on the subject, and WHO has explained the decision-making considerations.

🌿 [TAG-CO-VAC statement, 17 June 2022](#)

🌿 [WHO statement, 17 June 2022](#)

Q&A on regulation of COVID-19 vaccines

WHO and the International Coalition of Medicines Regulatory Authorities (ICMRA) have issued a joint statement explaining how vaccines are evaluated for approval by regulatory authorities and monitored thereafter. This is intended to help healthcare professionals answer questions from the public.

🌿 [Statement, revised 17 May 2022.](#)

Ukraine conflict

The war in Ukraine has implications for public health worldwide. Massive international resources are absorbed to support failing health systems locally and accommodate a stream of refugees arriving in other countries. The war increases public health risks within and outside Ukraine in various ways, for example by threatening food security and by increasing violence and human trafficking.

🌿 [Ukraine emergency \(WHO website\)](#)

🌿 [WMA/CPME/EFMA medical help fund](#)

Disease outbreaks

Two outbreaks with a global reach have emerged:

- **monkeypox outside endemic countries**, and
- **acute hepatitis of unknown cause in children**.

Both are new, atypical phenomena. The WHO disease outbreak news (DON) have links to further guidance and information.

🌿 DON on [Monkeypox \(17 June 2022\)](#)

[WHO Emergency Committee report \(25 Jun 2022\)](#)

🌿 DON on [Acute hepatitis of unknown cause in children \(24 Jun 2022\)](#)

Immunization gap

- UNICEF and WHO have warned of a risk of large outbreaks of measles and other vaccine-preventable diseases due to pandemic-related disruptions, increasing inequalities in access to vaccines, and the diversion of resources from routine immunization.

🌿 [Joint news release, 27 April 2022](#)

International events

WHO

World Health Organization

Seventy-fifth World Health Assembly

22-28 May 2022, Geneva, Switzerland, and online

The theme of this year's World Health Assembly (WHA) was "Health for Peace, Peace for Health". Decisions and resolutions were adopted on sustainable financing for WHO, health emergency preparedness and response, communicable and noncommunicable diseases and mental health, the health workforce, polio eradication and transition, medical devices nomenclature, and other issues. WHO Director-General Tedros Adhanom Ghebreyesus was elected for a second term.

[WHA75: Daily updates](#)

[Main documents](#)

ICH

International Council for Harmonization

ICH Assembly meeting

21-25 May 2022, Athens, Greece, and online

CIOMS is an ICH observer and was represented at the ICH Assembly by its Secretary General, Lembit Rägo. ICH welcomed the Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom as a new member, and the medicines regulatory authority of Algeria as a new observer. The Assembly reviewed the status of activity of all thirty-one ICH Working Groups and received updates on the implementation of the MedDRA terminology as well as training and communication activities.

[ICH press release, 1 June 2022](#)

SAVE THE DATE

2022 CoRE Scientific Conference: Patients as Partners for Health:

5-6 October 2022; Singapore (hybrid event)

This conference will focus on *Co-creating equitable access to health products and services*. Several [CIOMS Working Group XI](#) members are on the scientific committee, which is co-chaired by 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.

[Register here.](#)

IFMSA

10th Youth PreWorld Health Assembly

May/June 2020, virtual and hybrid meetings



(Above) The preWHA delegates at WHO Headquarters in Geneva
Image source: [IFMSA tweet](#)

CIOMS is a proud supporter of the Youth Pre World Health Assembly (Youth PreWHA), which is organized by the International Federation of Medical Students' Associations (IFMSA). Sixty youth advocates from 38 different countries were selected to participate in this year's event, which took place on six days in May before the World Health Assembly. CIOMS was represented by speakers at two events: Executive Committee member Otmar Kloiber co-hosted a panel discussion on "Universal health coverage as a multi-sectoral concept" on 18 May (photo below), and CIOMS Secretary-General Lembit Rägo delivered the keynote speech at the reflection session held on 4 June.

The annual Youth PreWHA aims to educate and empower future leaders while ensuring that the voice of youth is being heard at the most high-level global health decision-making event.



Participants at the panel discussion held on 18 May.

Focus on: Drug-induced liver injury (DILI)



DILI is a critical challenge in drug development and in the post-market setting. The CIOMS consensus report on DILI was published in 2020 (freely available [here](#)), and an e-learning course based on this report was launched in April 2020 (see box below).

The CIOMS DILI Working Group (2017-2020) was able to draw on existing collaborative initiatives, notably the [IQ-DILI initiative](#) presented below. Nine IQ-DILI experts were members of the CIOMS DILI group. Some of them are also contributing to the ongoing CIOMS Working Group on severe cutaneous adverse reactions to drugs (SCARs).

IQ DRUG-INDUCED LIVER INJURY (DILI) INITIATIVE



An affiliate of the **International Consortium for Innovation and Quality in Drug Development (IQ)**

Created in 2016, IQ DILI is the first industry-led effort focusing on clinical aspects of DILI. It aims to define evidence-based best practices for diagnosing, monitoring, managing, and preventing DILI. With a growing membership of currently 19 companies, IQ-DILI comprises a network of specialists who contribute their insights to develop pragmatic solutions that will benefit patients.

IQ DILI currently has [nine working groups](#) focusing on key topics of DILI such as abnormal baselines, causality assessment, and immunotherapy, as well as DILI in special populations and post-marketing risk mitigation and pharmacovigilance. [Six best practice publications](#) have been produced to date and are widely downloaded.

A strength of IQ-DILI is that it can draw on large amounts of data that have aggregated at member companies over time—a huge advantage when dealing with a rare condition such as DILI. Accordingly, the second stage of the IQ DILI Initiative is a cross-company clinical data-sharing

effort. The IQ DILI Working Groups have started discussing what data are needed to substantiate and advance best practices, and are developing research questions.

In its five years of existence, IQ DILI has established a successful network and is looking to a bright future. CIOMS and IQ DILI look forward to collaborating in times to come.

<https://www.iqdili.org>



(Above) Arie Regev, IQ DILI Co-founder and Chair emeritus, and vice-chair of the former CIOMS DILI Working Group, in a video marking the 5-year anniversary of IQ DILI.

(Below) The DILI e-learning modules. From 1 May to 30 June 2022, **516** learners enrolled in the course, **187** completed it successfully.

Drug induced liver injury (DILI)			
WELCOME			
Welcome	What is DILI?	Assessing DILI cases	Post-marketing surveillance
Clinical care	Herbal and dietary supplements	Reflection: Three case histories	Evaluation & certificate

New: CIOMS/UMC e-learning course on DILI


We are pleased to announce the new e-learning course on drug-induced liver injury (DILI), the first to be produced in collaboration between CIOMS and the Uppsala Monitoring Centre (UMC). The course is free of charge for those working at pharmacovigilance centres and public sector institutions, and will soon be made available to for-profit organisations for a fee.

[Access the course here.](#)

Publications

Draft U.S. FDA guidance on gene therapy

The U.S. Food and Drug Administration (FDA) has released two draft guidance documents on human gene therapy products, for developers and manufacturers. Both documents have been published for comment purposes.

- [Human Gene Therapy Products Incorporating Human Genome Editing](#); and
 - [Considerations for the Development of Chimeric Antigen Receptor \(CAR\) T Cell Products](#).
-  [Search for FDA Guidance Documents](#)

CIOMS cited

Scientific articles

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- Green TJ, Walker LE, Turner RM. **A European cross-sectional survey to investigate how involved doctors training in clinical pharmacology are in drug concentration monitoring.** *Eur J Clin Pharmacol.* 2022;1-9. doi:10.1007/s00228-022-03316-z
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- Zola Matuvanga T, Larivière Y, Lemey G, et al. **Setting-up an Ebola vaccine trial in a remote area of the Democratic Republic of the Congo: Challenges, mitigations, and lessons learned.** *Vaccine.* 2022;40(25):3470-3480. doi:10.1016/j.vaccine.2022.04.094

Collection

Bate A, Luo Y (editors). **Role of Artificial Intelligence and Machine Learning in Pharmacovigilance.** *Drug Saf.* 2022. *The sixteen articles in this collection provide a comprehensive coverage on how emerging technologies can affect work tasks and further improve the field of pharmacovigilance.*

Books

WHO. **Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance.** Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. [WHO website](#)

Perspective

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). **IFPMA Perspective on Clinical Research in Resource-Limited Settings.** 9 June 2022. IFPMA congratulates CIOMS and its technical working group for the comprehensive report on this topic. www.ifpma.org/resource-centre/clinical-research-in-resource-limited-settings/

In memoriam

Sten Olsson

It is with great sadness that CIOMS learned about the death of Sten Olsson, founder member of the Uppsala Monitoring Centre (UMC), where he worked for almost 40 years in various positions related to developing pharmacovigilance systems globally within the expanding WHO Programme for International Drug Monitoring.

Sten was President of the International Society of Pharmacovigilance (ISoP) from 2016-19. He supported international cooperation on drug safety in various ways throughout his career.

UMC and CIOMS have worked together for many years to advance medicines safety, and Sten has contributed to CIOMS activities



Sten as pictured in an interview on the occasion of his retirement from UMC: [Down memory lane. Four decades of building drug safety](#). Uppsala Reports No. 75, 2017.

since the days of CIOMS round table conferences in the 1990s. More recently he was a member of the CIOMS [Working Group on Vaccine safety](#), which concluded its work in 2017, and the CIOMS [Working Group XI on Patient involvement](#) in the development, regulation and safe use of medicines, which has published its draft report earlier this year.

Sten was passionate about promoting medicines safety, especially in developing countries. He was a respected and humble

global ambassador of pharmacovigilance. He was also an exceptional teacher, mentor, colleague and friend to many in Sweden and abroad. He leaves behind three sons and a brother as well as their families.

[Sten's memorial site](#)

Brian S. Dillman

We are shocked and saddened to hear of the loss of Brian Dillman, who died at age 49 after being struck by a vehicle near his family's home in Indianapolis, United States.

Brian was a member of the [CIOMS Working Group on MedDRA labelling groupings](#) (MLG), to which he contributed his experience as Clinical Research Physician at Eli Lilly's Global Patient Safety organization. Having joined the company in 2009, he continued to work as an emergency room physician on a part time basis.



Image from: Franciscan Health

The CIOMS Working Group is devastated about Brian's tragic and untimely death. Brian was a kind and respected team member as well as a wonderful person, and working with him over the past three years has been the group's great honour and pleasure. He was friendly and compassionate, and had the great ability to listen to people and find compromises. He always saw the best in others, and his good nature brought people together.

Brian is survived by his wife, their daughter, a sister, and his parents.

[Brian's memorial site](#)

News from the CIOMS Secretariat

XXV CIOMS General Assembly

1 June 2022 (Virtual meeting)



The XXVth session of the CIOMS General Assembly was held in conjunction with the 89th session of the CIOMS Executive Committee. Participants were given an update on achievements since June 2021, which are also reflected in the CIOMS Newsletters (NL, see links below). Some milestones were:

- CIOMS Working Group report on Clinical research in resource-limited settings (NL #34),
- Cumulative pharmacovigilance glossary (NL #34)
- CIOMS/UMC e-learning course on drug-induced liver injury (see page 4),
- 2021 CIOMS award for the best scientific paper by a medical student (NL #36),
- draft CIOMS WG report on Patient involvement published for comment (NL #37), and
- four new CIOMS Working Groups (pp. 1 and 8).

Several delegates commended CIOMS for doing exceptionally well in the challenging circumstances of recent years.

The voting members elected three new representatives to the [CIOMS Executive Committee](#): **Cordula Landgraf** for the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP), **Adelheid Schneider-Gilg** for the Medical Women's International Association (MWIA), and **Manal Younus** for the International Society of Pharmacovigilance (ISoP). Hervé le Louët and Samia Hurst were confirmed as CIOMS President and Vice President respectively. The participants also approved the CIOMS financial accounts and budget for 2022.

<http://cioms.ch>

Just a click away ...

CIOMS topic areas and Working Groups (WG)

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

- Ethics**
 - Good governance practice for research institutions
 - Educational standards
- Product development**
 - Patient involvement in the development, regulation and safe use of medicines (WG XI)
 - MedDRA labelling groupings
 - Benefit-risk balance for medicinal products (WG XII)*
- Pharmacovigilance**
 - Real-world data and real-world evidence in regulatory decision-making (WG XIII)
 - Severe cutaneous adverse reactions (SCARs)
 - NEW: Artificial intelligence in pharmacovigilance



WG XIV



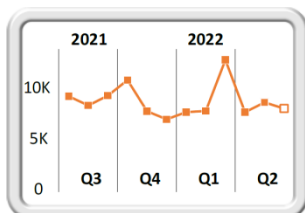
WG XII

*From Working Group (WG) XII: CIOMS congratulates WG member **Steffen Thirstrup** on his appointment as Chief Medical Officer of the European Medicines Agency (EMA).

[EMA News, 1 June 2022](#)

Find us on the web:

48 583 visitors from 178 countries



Website visitors each month
 □ = extrapolated to the end of June

----- Second quarter of 2022 (as of 22 June) -----

Top downloads of CIOMS publications

1	Cumulative CIOMS pharmacovigilance glossary	307
2	CIOMS 2016 Ethical Guidelines	209
3	Practical aspects of signal detection (CIOMS VIII)	165
4	Drug-induced liver injury	143
5	Managem't of safety information from clinical trials (CIOMS VI)	132
6	Preparing core clinical safety information on drugs (CIOMS III/IV)	124
7	Clinical research in resource-limited settings	116
8	Practical approaches to risk-minimisation (CIOMS IX)	95

See all [CIOMS publications](#)

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