What's on @ CIOMS
COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES
1949-2024 75
WWW.CIOMS.CH March 2024 | **Newsletter** # 45

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Just published

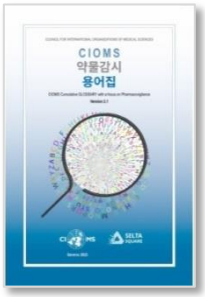
CIOMS Working Group report on
Introduction to MedDRA Labeling Grouping (MLG)

The Medical Dictionary for Regulatory Activities (MedDRA) terminology is useful for precise coding of adverse events of medicines for data analysis. However, its high granularity can obscure the communication of adverse reactions in product labeling for healthcare practitioners and patients. At present, there are no agreed-upon conventions that describe which adverse reaction terms may be appropriate to group together.

The CIOMS consensus document proposes principles and points to consider the creation and use of groups of MedDRA terms, or "MedDRA Labeling Groupings (MLGs)", in medical product prescribing information. It is envisaged that the use of the recommendations would be voluntary and applied to product labels in a manner that is consistent with existing regulatory frameworks.

☞ **Introduction to MedDRA Labeling Grouping (MLG).** https://doi.org/10.56759/hmku5307

Translations



CIOMS Cumulative glossary in Korean

This translation was prepared as part of an innovative automated pharmacovigilance (PV) system launched by the South Korean company SELTA SQUARE in 2022. It is also made available separately as a free PDF download. We thank SELTA SQUARE for their support.

☞ CIOMS Cumulative glossary, with a focus on pharmacovigilance (version 2.1) in Korean

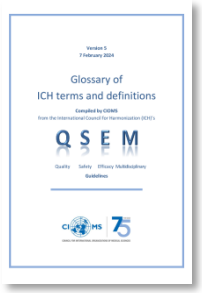
☞ **IBM case study on SELTA SQUARE's PV system**

CIOMS International ethical guidelines in Polish

This translation was produced with the kind support of Jagiellonian University Press. The guidelines are now available in eleven languages (see page 8).

☞ **Polish translation of the CIOMS International ethical guidelines on health-related research involving humans.**

Living document



CIOMS Glossary of ICH terms and definitions (Version 5)

This glossary combines the terms and definitions included in the publicly available guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The ICH Guidelines are developed by scientific consensus between regulatory and industry experts, and the final guidelines are implemented in ICH member states. The glossary provides a useful resource for both CIOMS and ICH Working Groups, as well as other stakeholders.

☞ https://doi.org/10.56759/eftb6868

CIOMS Working Group news

☞ All Working Groups

In-person meeting

First quarter of 2024

Artificial intelligence in pharmacovigilance

CIOMS Working Group XIV

8th Meeting
7-8 March 2024, Geneva (Switzerland)

This group is working to provide a framework for the critical appraisal, implementation and maintenance of artificial intelligence (AI) solutions for pharmacovigilance. At a time when data analytic capabilities are growing exponentially, and AI is being used in various areas of biomedical research and practice, there is a need for guidance to ensure that future learning algorithms in pharmacovigilance are robust, reliable and reproducible.

☞ **Working Group webpage**

(**Above**) The meeting participants

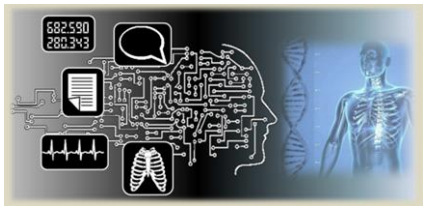
Related:

WHO guidance on large multimodal models (LMMs)

WHO has released new guidance on the ethics and governance of large multimodal models (LMMs), a type of fast-growing artificial intelligence technology with many applications across healthcare.

LMMs can improve healthcare, but they also have risks that must be fully accounted for. Based on guidance published in 2021, the new document outlines over 40 recommendations for consideration by governments, technology companies and healthcare providers.

☞ **WHO news release, 18 January 2024 | Link to the 2024 guidance**



(**Above**) LMMs can mimic human communication and carry out tasks they were not explicitly programmed to do. They can accept inputs such as text, videos or images, and generate outputs that are not limited to the type of input.

EU Artificial Intelligence Act

On 13 March 2024 the European Parliament adopted the world's first binding law on artificial intelligence. It limits the use of biometric identification systems, bans social scoring, defines obligations for high-risk systems—such as uses in healthcare—and entitles consumers to launch complaints and receive meaningful explanations. Various steps are still to be completed until the different parts of the law enter into force.

☞ **European Parliament press release, 13 March 2024.**
Artificial Intelligence Act

Based on an image by Sofia Terzoni from Pixabaycc

Virtual Working Group meetings

First quarter of 2024

11 January 2024	12 February 2024	26 February 2024
Artificial intelligence in pharmacovigilance	**Education and training for health professionals participating in medicines development**	**Pharmacoepidemiology for public health**
CIOMS Working Group XIV		CIOMS Working Group XV
7th Meeting	7th Meeting	2nd Meeting

CIOMS@ International events

Focus on: Bioethics

17th Global Forum on Bioethics in Research

28-29 November 2023, Montreux (Switzerland)

(**Above**) Participants at the 17th Forum. Rieke van der Graaf, Secretary of the former CIOMS Working Group on Bioethics, was invited to represent CIOMS.

The theme of this forum was "Ethics of health research priority setting". It was inspired by the problem that global resources on health are unfairly distributed. Participants broadly discussed how research priority setting can help to distribute research funds more fairly. There was specific attention to national research priority setting, ways to involve and prioritize marginalized voices in research, the governance of priority setting in research, and ethical and practical challenges.

☞ **Conference website**

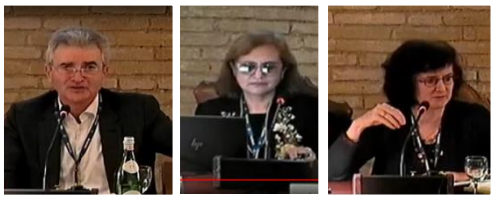
WMA Conference on the Revision of the Declaration of Helsinki

18-19 January 2024, Vatican City

This event was one of a series of regional and topical expert meetings organized by the World Medical Association (WMA) to inform the ongoing revision of its Declaration of Helsinki (DOH), this time with a focus on research in resource-poor settings. A public consultation took place in early 2024; a second round of comments will be sought at a later stage.

The 2016 CIOMS *International ethical guidelines on health-related research involving humans* and the 2021 guidelines on *Clinical research in resource-limited settings* were mentioned by several speakers, as they include useful recommendations for the implementation of the DOH in low-resource settings.

☞ **Conference website**



(**Above**) Among the speakers were Dominique Sprumont, Ames Dhai, and Raffaella Ravinetto, all of whom have contributed to past CIOMS Working Groups on ethical topics. Images from 1st Day a.m. and p.m. recordings
Also available: 2nd Day a.m. recording

Public lecture on applying the CIOMS research ethics principles

20 February 2024, Johannesburg (South Africa)

(**Above**) Professor van Delden, during his lecture at the University of the Witwatersrand. (Images: ASSAf Facebook page)

Hans van Delden, past CIOMS President and Chair of the former CIOMS Working Group on Bioethics, was the guest of honour at this event. Also present, Dominique Sprumont, Chair of the CIOMS Working Group that produced the 2023 *International guidelines on good governance practice for research institutions*.

The lecture and subsequent panel discussion explored how to apply the principles of the 2016 CIOMS/WHO international ethical guidelines. The event attracted about 150 participants in person and almost 200 online.

☞ **Academy of Science of South Africa (ASSAf) event webpage | Recording**

CIOMS@ International events (continued)

DIA Global Pharmacovigilance and Risk Management Strategies Conference

5–7 February 2024, Baltimore, U.S.


(**Above**) CIOMS Working Group XII members Hong Yang and Richard Forshee from the U.S. FDA introduced the draft CIOMS report.

Session 7 of this conference focused on the draft CIOMS Working Group XII report on benefit-risk assessment. The participants discussed how to put into place a structured benefit-risk assessment framework all along a drug's lifecycle, taking into account patient-centric endpoints when designing clinical trials.

☞ - **Conference website**
- **Draft CIOMS report** (published for consultation in June 2023)
- **News feature,** Regulatory Focus™, 7 February 2024.

Now out:

EUPV 2023 speaker abstracts

☞ **The 7th European Pharmacovigilance Congress: speaker abstracts. Ther Adv Drug Saf. 2024; 15: 20420986231225509.**
https://doi.org/10.1177/20420986231225509

(**Right**) CIOMS Secretary-General Lembit Rägo chaired the opening session on 'Evolving Pharmacovigilance Strategies'.

Save the date

17 May 2024
Washington DC (United States)

2024 Drug Induced Liver Injury (DILI) Conference

Organized by IQ DILI, an affiliate of the International Consortium for Innovation and Quality in Pharmaceutical Development, focused on defining best practices to detect, monitor, manage and prevent (DILI). IQ-DILI experts include several members of the former CIOMS DILI Working Group.

24– 28 August 2024
Berlin (Germany)

ISPE Annual Meeting

Annual meeting of the International Society of Pharmacoepidemiology
☞ **www.pharmacoepi.org/meetings/annual-conference/ispe-2024**
Call for abstracts

1– 5 October 2024
Montreal (Canada)

ISoP Annual Meeting

Annual meeting of the International Society of Pharmacovigilance
☞ **https://isoponline.org/annual-meetings/isop-2024/**

News roundup

Based on an image by Nicolás from Pixabay

Europe

Artificial Intelligence Act

The adoption of this landmark law makes Europe a leader in the field of regulating artificial intelligence. ☞ More on page 3

EMA European Medicines Agency

→ **Find more news in the EMA newsletters.**

Big data steering group (BDSG)

2023 report

The BDSG advises the EMA on "big data"-related initiatives such as the DARWIN EU® coordination centre, the EU framework for data quality and representativeness, discovery and use of real-world data, and many more. Read their 2023 report and recommendations here:

☞ **Big Data Steering Group (BDSG): 2023 report.**

Human medicines highlights

2023 report

The EMA has published its annual overview of information on authorization of new medicines and safety-related measures. In 2023 the Agency recommended 77 new products, including two vaccines against respiratory syncytial virus (RSV) and the first medicine using the CRISPR/Cas9 gene-editing technology. EMA also adopted two positive opinions for medicines for use outside the EU.

☞ **EMA. Human medicines highlights 2023.**

Evaluating anticancer products

Revised guideline

The EMA guideline on evaluation of anticancer products has evolved over the years to include new focus areas. The newly adopted 6th revision addresses biomarker-guided medicinal product development and recent designs in oncology studies.

☞ **Guideline on the clinical evaluation of anticancer medicinal products.** 18 November 2023.

CIRS Centre for Innovation in Regulatory Science

Medicines development

CIRS workshop

At this workshop, regulators, HTA agencies and industry discussed new ways of working together in a rapidly changing global landscape. Recommendations were made on how to adapt to new technologies and ways of generating evidence, particularly regarding advanced therapy products, digital health technologies and real-world data, and how to promote alignment and harmonisation.

☞ **CIRS announcement, 17 January 2024.**

Regulatory reliance

CIRS briefing

Regulatory reliance is recognized as a strategic necessity to speed up assessment of medicines worldwide. This briefing reviews the use and impact of risk-based review routes in ASEAN, Saudia Arabia and Australia, and proposes practical steps for agencies to consider when implementing reliance mechanisms in their frameworks.

☞ **CIRS R&D Briefing 91**. 21 February 2024.

Rare disease products

CIRS workshop

At this multi-stakeholder event it was suggested, among other things, that to align stakeholder needs around access to rare disease products, a "working with patients" code of conduct could be created, building on existing guidance such as the CIOMS Working Group XI report on Patient involvement.

☞ **CIRS Workshop synopsis**

CIOMS Secretariat news

The CIOMS student award is now entering its seventh year. Read more here.

CIOMS student award

The 2023 CIOMS award of US$ 1500 for the best scientific article published by a medical student in the areas of pharmacovigilance or research ethics goes to **Clara Portwood** from the University of Oxford, United Kingdom.

Clara is the first author of a systematic review and meta-analysis assessing adverse perinatal outcomes in pregnant women living with HIV.[1] Her paper touches upon an ongoing and serious public health issue. It underscores the importance of long term monitoring of antiretroviral therapy, including old drugs, and of conducting further research to understand and minimize adverse perinatal outcomes.

The findings of this large study contribute to the very limited research data on the safety of interventions in pregnant women living with HIV. Clara's paper is referenced in the U.S. clinical guidelines on treating HIV during pregnancy and preventing perinatal transmission.

[1] Portwood C, Murray C, Sexton H, et al. **Adverse perinatal outcomes associated with HAART and monotherapy**. AIDS. 2022;36(10):1409-1427. doi:10.1097/QAD.0000000000003248

Clara Portwood is a final year undergraduate student undertaking a Bachelor of Medicine and Bachelor of Surgery (BMBCh). She holds a first-class BA in Medical Sciences from the University of Oxford. Her research interests include adverse drug reactions, patient safety and cardiovascular medicine. Clara aims to pursue internal medicine training with a view to becoming a cardiologist.

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1/1– 26/3/2024

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Ongoing CIOMS Working Groups (WG)

Meeting minutes are published on the groups' webpages.

- Pharmacoepidemiology for public health (WG XV)
- Artificial Intelligence in Pharmacovigilance (WG XIV)
- Educational standards for health professionals participating in medicines development
- Severe Cutaneous Adverse Reactions to Drugs (SCARs)
- Real-World Data and Real-World Evidence in Regulatory Decision Making (WG XIII)
- Benefit-Risk Balance for Medicinal Products (WG XII)
- MedDRA Labelling Grouping — **completed**

Top ten CIOMS publications

1/1– 26/3/2024 — Downloads

Living document: Glossary of ICH terms and definitions (Versions 4 and 5)		1502
2024	**New:** Introduction to MedDRA Labelling Grouping (MLG)	929
2023	CIOMS Cumulative glossary, with a focus on pharmacovigilance (Version 2.1)	418
2023	International guidelines on good governance practice for research institutions	278
2016	International ethical guidelines for health-related research involving humans *	206
2005	Management of Safety Information from Clinical Trials ***	177
2016	Development and Rational use of Standardized MedDRA Queries (SMQs), 2nd Edition	167
2020	Drug-Induced Liver Injury (DILI)	125
2010	Practical Aspects of Signal Detection in Pharmacovigilance	122
2022	Patient involvement in the development, regulation and safe use of medicines (WG XI) ***	120

* Also available in: Arabic, Chinese, French, Japanese, Korean, Polish (**new**), Portuguese, Russian, Spanish, Ukrainian

** Also available in Chinese

*** Final print version now available in Japanese

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