What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

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In this newsletter

Just published

CIOMS Glossary of ICH Terms and Definitions

Version 10

The newly updated CIOMS Glossary of ICH terms and Definitions is available for download. Combining definitions from across the current, publicly available guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), this glossary is a useful reference for ICH Stakeholders and CIOMS Working Groups.

☞ **The glossary can be accessed via: the CIOMS website or the ICH website**

In Japanese: MedDRA Labeling Grouping

The 2024 CIOMS report *Introduction to MedDRA Labeling Grouping (MLG): A standardized approach to grouping adverse reactions in product safety labels* is now available in Japanese.

The Medical Dictionary for Regulatory Activities (MedDRA) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use is used in product safety labeling to describe adverse reactions (ARs). However, because of MedDRA's granularity, preferred terms (PTs) relevant to a single AR may be located in different areas of the terminology. These terms may represent the same clinical concept and therefore warrant grouping for communication in product safety labels (PSLs).

MedDRA does not currently provide groupings of AR terms intended for use in PSLs. As a result, clinically equivalent ARs may be presented as separate terms, potentially obscuring important safety information. There is therefore a need for standardized groupings of AR terms that describe the same medical concept. Although some organizations have developed their own grouping approaches, the absence of agreed conventions has led to considerable variability. To address this issue, a CIOMS Working Group developed international consensus principles for a new type of grouping, published in 2024 as *Introduction to MedDRA Labeling Grouping (MLG): A Standardized Approach to Grouping Adverse Reactions in Product Safety Labels* (also available in **Chinese**).

☞ **In Japanese: Introduction to MedDRA Labeling Grouping (MLG)**

CIOMS webinars

Drugs and the Microbiome: How Do They Interact?

10 June 2026

The microbiome as a determinant of health

Recent advances in metagenomics, metabolomics and systems biology have transformed the human microbiome — the intricate and dynamic community of micro-organisms living in and on our bodies — from a scientific curiosity into a

central determinant of human health. It is now evident that the microbiome does not merely coexist with the human host: it influences susceptibility to a broad range of diseases, actively participates in medicine metabolism and shapes therapeutic outcomes.

The human microbiome challenge for…

Healthcare professionals: *The lack of standardized clinical practice guidelines, and of a deep mechanistic understanding of the human microbiome, makes "translation" of research for patient care difficult and also increases the risk of inconsistent clinical decisions.*

The public/patients: *Misinformation and marketing hype surrounding products such as probiotics — widely used dietary supplements that are promoted as positively influencing gut health and microbiota diversity — can lead to therapeutic misconceptions and inappropriate self-care. This knowledge deficit creates uncertainty and can negatively impact treatment outcomes.*

Pharmaceutical industry and public health authorities: *Emerging therapies with microbiome impact raise concerns about long-term safety and generate complex ethical and regulatory questions.*

Growing evidence demonstrates a bidirectional and clinically important interaction between medicinal products and the human microbiome. Medicines designed to target either specific human molecules and cells, or pathogens, can induce profound and long-lasting alterations in microbial communities. For example, beyond classical antibiotics, many host-targeted drugs, including proton pump inhibitors, selective serotonin reuptake inhibitors, antipsychotics, opioids and statins, can significantly alter the composition and function of the gut microbiome. Gut microorganisms are themselves now recognized as active contributors to drug metabolism, influencing drug activation, inactivation, toxicity and inter-individual variability in treatment response.

In brief, drug and microbiome interactions have far-reaching implications for pharmacokinetics, pharmacodynamics, antimicrobial resistance, treatment outcomes, regulatory science and public health policy.

Unanswered questions

Yet despite rapid scientific progress, microbiome interactions are not yet systematically factored into drug development, benefit–risk assessment, or post-marketing surveillance, leaving many questions unanswered for many different groups working in health or on health issues

Recognizing the urgency of the above issues, CIOMS organized a webinar with two aims. Firstly, to address knowledge gaps concerning human microbiome issues by providing an authoritative overview of current evidence on how drugs affect the microbiome and how the microbiome influences drug metabolism, focusing on regulatory and pharmacovigilance implications. Secondly, to collect views and ideas regarding the potential topics that could be further elaborated by a potential CIOMS working group on optimal management of drug effects on the microbiome and microbial effects on drugs.

Held on 10 June 2026, the webinar featured presentations by renowned experts in their field and generated many questions.

Left to right: Experts and panellists who participated in the CIOMS microbiome webinar: Professor Elin Org (University of Tartu, Estonia; Professor Lisa Maier (University of Tübingen, Germany); Dr Michael Zimmermann (European Molecular Biology Laboratory, Heidelberg, Germany); Dr Lembit Rägo (Secretary-General, CIOMS); Dr Oliver Aasmets (University of Tartu, Estonia); Kertu Liis Krigul (Research Fellow, University of Tartu, Estonia).

Artificial Intelligence in Pharmacovigilance

20 April 2026

Working Group XIV: Artificial Intelligence in Pharmacovigilance held its third and final webinar on 20 April 2026 to introduce and explain the main concepts of its report. Its three webinars were joined by over 1700 attendees, representing 105 countries. Feedback survey results indicated that the webinar was well received with 67% of respondents indicating that the webinar exceeded expectations and 83% of respondents indicating that it met all or most or their objectives. The survey results have been added to a growing data resource to guide development of future webinars.

☞ **Webinar recording**

CIOMS Working Group updates

Working Group XVI: Development Safety Update Report convened its fifth meeting virtually on 23 April 2026. It reviewed updates relevant to ongoing report development and subgroup activities, including discussion on emerging European developments related to safety reporting in combined studies involving medicinal products and medical devices. It was emphasized that increasing complexity and workload associated with additional safety reporting requirements could have implications for smaller organizations and companies and implementation challenges may differ substantially between large pharmaceutical companies and smaller organizations. The next meeting of the group will be held on 28 and 29 September 2026, in Tallinn, Estonia.

☞ **Further information on Working Group XVI**

Working XVII: Long-term Safety of Medicinal Products held a virtual meeting on 1 June 2026 and in-person meeting in Geneva on 29 and 30 June 2026. Both subgroups reported substantial progress in developing draft chapters, with several sections already available for cross-review.

☞ **Further information on Working Group XVII**

CIOMS@ international events

ISoP Mid-Year Symposium 2026: Collaboration in Pharmacovigilance in an Evolving Information Environment

9 & 10 June 2026 – Hatfield, UK

Held In Hatfield, UK, this ISoP Mid-Year Symposium brought together experts and professionals in the field of pharmacovigilance and drug safety, to foster collaboration and knowledge sharing.

CIOMS President, Dr Stella Blackburn spoke on the ongoing contribution of CIOMS to the evolution of pharmacovigilance, which is now a global, technology-enabled system for the detection, assessment, understanding and prevention of adverse drug reactions.

Dr Blackburn explained the distinction between standards, guidelines and guidance. Standards describe what is required. Guidelines recommend practices for achieving a desired outcome, while guidance provides practical advice on how to implement those practices. She noted, however, that pharmacovigilance requirements are stipulated by regulatory authorities worldwide

and that keeping pace with and complying with these requirements can be challenging. She went on to outline how CIOMS supports regulators by developing internationally recognized guidelines and guidance that helps standardize how medicines safety is monitored, assessed and communicated throughout a product's lifecycle.

CIOMS will also participate in ISoP's 2026 Global Meeting, to be held 22–25 September in San José, Costa Rica: "Ecosystems of trust: Pharmacovigilance for a Healthier World".

☞ **ISOP 2026 Global Meeting**

CIOMS at World Health Assembly: Pharmacoepidemiology for Public Health Decision-making

22 May 2026 – Geneva, Switzerland

On the occasion of the 79th World Health Assembly (WHA79) — 18–23 May 2026 in Geneva — CIOMS held an informal side event: "Empowering Pharmacoepidemiology for Public Health Decision-making". The session served as an introduction to the upcoming report of CIOMS Working Group XV which explores what pharmacoepidemiology can (and cannot) contribute to the work of public health authorities, regulators, academia and industry.

Three Working Group members — Professors Yola Moride, Dr Bernard Bégoud and Dr Hervé Le Louet — described the opportunities and challenges for pharmacoepidemiology today. The new report, which is scheduled for publication in late 2026 will not be a technical guideline aimed at providing instruction on how to carry out a pharmacoepidemiological study, but rather how to evaluate when a pharmacoepidemiological study would be truly useful for public health decision-making, including during times of emergency.

Left to right: Professor Yola Moride (Research Professor, Center for Pharmacoepidemiology and Treatment Science, Rutgers, The State University of New Jersey, USA); Professor Hervé Le Louët (CIOMS Immediate Past President); Professor Bernard Bégaud (University of Bordeaux, France).

State Agency of Medicines, Estonia, celebrates 35 years

11 April 2026 – Tartu, Estonia

Estonia's State Agency of Medicines celebrated its 35th anniversary on 11 April 2026, with a conference titled "Innovation doesn't wait". The event explored current and future developments in medicines and considered how best to balance fostering of innovation and ensuring the safety of medicinal products.

In her welcome address, the Agency's current Director-General, Dr Katrin Kiisk, described the Agency's role as extending beyond regulation to also support development. It does this by nurturing an environment where good ideas can grow, reach implementation, and ultimately benefit patients. "Fixed ways of thinking do not support progress," she continued. "Collaboration between scientists, regulators and technology experts is key to enabling new initiatives and ensuring that artificial intelligence and data-driven solutions are used wisely and responsibly in the development of the pharmaceutical sector."

A range of stakeholders from Estonia and beyond — including representatives of patient

Above: Dr Lembit Rägo (founding Director General Estonia's State Agency of Medicines and currently Secretary-General of CIOMS), and Dr Katrin Kiisk (current Director-General, of Estonia's State Agency of Medicines).

groups, industry, academia and the Swedish Medical Products Agency — shared their perspectives on different aspects of medicines development. The programme also featured a lively panel discussion on the role of a small medicines agency within the large EU system.

Panellists discussed Estonia's contributions to European medicines regulation — especially in terms of its expertise — as well as the benefits that Estonia's regulatory activities gain from collaboration with numerous agencies.

Dr Lembit Rägo, Secretary-General of CIOMS, and the State Agency's founding Director-General, recalled that the Agency was one of the few state institutions to be established even before Estonia regained its independence. Given both the benefits and risks that innovative, new medicines may incorporate, he highlighted the CIOMS report on evaluation of the benefit–risk balance of medicinal products. He also outlined what he considers to be the most promising directions for future benefit–risk assessment.

Looking back on her tenure as the Agency's second Director General, Dr Kristin Raudsepp emphasized that the Agency did not measure its work in hours but in terms of its responsibility to safeguard human health and safety and to maintain public trust.

☞ **Estonian Agency of Medicines**

DIA Global Meeting 2026

14–18 June 2026, Philadelphia, USA

On 15 June 2026, recommendations in *Artificial Intelligence in Pharmacovigilance* were presented by five members of CIOMS Working Group XIV, which produced this report. They addressed governance principles, transparency, robustness, fairness and regulatory expectations using real examples. (Both the report and associated webinars have met with considerable interest.)

On 17 June 2026, a panel — including Dr Claudia Ana Ianos, member of CIOMS Working Group XII: Benefit–risk Balance for Medicinal Products — discussed benefit–risk planning and implementation of benefit–risk guidelines available from CIOMS and the US Food and Drug Administration.

Left to right: Phil Tregunno (MHRA), Dr Niklas Noren (UMC), Beth MacEntee-Pileggi (Johnson & Johnson), Dr Walter Straus (Moderna) and Benny Ling (Health Canada), members of CIOMS WG XIV and presenters at DIA's 2026 Global Meeting.

Save the date

RAPS Convergence 2026
Charlotte, NC, USA: 15 & 16 September 2026

Convergence offers 100+ educational and networking sessions where expert speakers share insights designed to assist participants at every stage of the regulatory process, across sectors and regions. Session tracks will cover: pharmaceuticals and biologics; topics of broad interest; medical devices and in vitro diagnostics; and skill building. Preconference workshops will be held on 14 & 15 September.

☞ **Programme information and registration**

8th International Clinical Trials Methodology Conference
Birmingham, UK: 14–17 September 2026

ICTMC is a leading international platform for researchers and practitioners to present the very latest in trials methodology. This conference is relevant for those working in: trial design; biostatistics; adaptive methods; evidence synthesis; trial operations; patient/public involvement; or health methodology.

☞ **Programme information and registration**

DIA Singapore Annual Meeting 2026
Singapore: 16 & 17 September 2026

The meeting will bring together regulators, industry leaders, and clinical experts to explore key developments shaping the future of healthcare in Asia. Discussions on modern trial modalities, regulatory innovation and next-generation technologies will provide insights into how to accelerate patient access while maintaining data integrity, safety and operational excellence.

☞ **Programme information and registration**

25th ISoP Global Meeting: Ecosystems of Trust: Pharmacovigilance for a Healthier World
San José, Costa Rica: 22–25 September 2026

The conference will offer an extensive programme including four pre-conference courses, plenary sessions and multiple parallel sessions to address key pharmacovigilance themes such as safety in special populations, digital transformation and AI, evidence generation, risk management, regulatory science and ethics. International experts from regulatory authorities, academia, industry, clinical practice and patient organizations will share cutting-edge knowledge and real-world experience on medication errors, medical devices, vaccines and public health, wider pharmacovigilance horizons, regional advances, and both patient and professional development.

☞ **Programme information and registration**

AfriSummit 2026
Nairobi, Kenya: 28 September–2 October 2026

This summit actually features two dedicated summits: PharmaReg AfriSummit on 29 & 30 September and MedDevReg AfriSummit on 1 & 2 October. It aims to bring together key stakeholders from the public and private sectors to discuss and move forward Africa's regulatory agenda.

☞ **Programme information and registration**

TOPRA Symposium 2026

Utrecht, The Netherlands: 19–21 October 2026

This symposium will bring together regulatory affairs professionals and key thought leaders to discuss the important topics affecting the regulatory affairs ecosystem.

☞ **Programme information and registration**

Regulatory news roundup

ACT EU Accelerating Clinical Trials in the European Union

New guidance: conduct of clinical trials in public health emergencies

ACT EU has published a draft guidance document outlining how clinical trials should be conducted during public health emergencies (PHEs). The guidance is intended for sponsors and all parties involved in the design and conduct of clinical trials in the EU. The advice is offered through increased coordination between the European Medicines Agency's Scientific Advice Working Party and the Heads of Medicines Agencies Clinical Trials Coordination Group.

This is the first guidance on PHEs to reflect the EU's current legislative framework as well as relevant guidelines from the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. It recommends a harmonized approach to ensure that clinical trials can be initiated, adapted and continued efficiently and safely when public health emergencies arise.

The guidance proposes regulatory mechanisms — including justifiable regulatory flexibilities — to accelerate the authorization of new clinical trials and the approval of modifications to ongoing trials during a PHE. It also provides guidance for situations in which trial participants can be transferred across investigational sites.

☞ **Guidance on the conduct of clinical trials during public health emergencies**

AMA African Medicines Agency

AMA & WHO launch landmark framework on regulation and access

The African Medicines Agency (AMA) and the World Health Organization have announced the launch and signing of a Framework Agreement for Collaboration, marking a major milestone in efforts to strengthen regulatory systems and improve access to safe, effective and quality-assured health products across Africa.

Signed in May 2026, the Agreement builds on the renewed African Union–WHO Memorandum of Understanding from May 2025, reaffirming a longstanding and strategic partnership. It provides the foundation for joint operational plans over the next 3–5 years, setting out priority areas of collaboration, timelines and deliverables to support regulatory system strengthening at national, regional and continental levels.

A central objective is to streamline regulatory processes across the continent, to reduce duplication and enable faster approval of medical products.

☞ **Further information**

EC/EU European Commission/European Union

Critical Medicines Act: provisional agreement

In March 2025, the European Commission proposed the Critical Medicines Act (CMA) to improve the availability, supply and production of critical medicines within the EU. The CMA also aims to increase access to other medicines of common interest, such as those for rare diseases, and to address the unavailability in certain markets of some needed medicines.

The Council of the European Commission and the European Parliament reached political agreement on the CMA in May 2026. This marked an important milestone in strengthening the resilience of Europe's health sector by preventing medicine shortages and improving the security of supply of critical medicines across the EU.

The CMA will promote the diversification of supply chains and support pharmaceutical manufacturing within the EU, while enabling Member States to cooperate more closely to improve access to medicines in Europe. The CMA complements existing initiatives to address medicine shortages and strengthen supply in the EU, in particular the recently adopted pharmaceutical reform.

The political agreement is now subject to formal approval by the European Parliament and the Council.

☞ **Further information**

Progress against new clinical trial targets

The European Commission (EC), the Heads of Medicines Agencies (HMA) and EMA have published their first report tracking progress against the new clinical trial targets of the European Union (EU). Established in 2025, these targets aim to strengthen the EU's position as a leading destination for clinical research, while improving patients' timely access to innovative medicines.

Covering activity from 1 January 2026 to the end of March 2026, the report highlights the following:

- 19 multinational clinical trials have been authorized in addition to the historical average, bringing the EU closer to its goal of 500 extra multinational trials by the end of 2030.
- Faster recruitment timelines: currently, 40.5% of the total number of clinical trials recruit participants within 200 days from application submission. The EU target is 66% by 2030.
- The new clinical trial targets are aligned with the EU Biotech Act proposed by the EC. One of the key changes under this initiative is the acceleration of clinical trial authorization processes across countries. Complementary network initiatives, such as FAST-EU (Facilitating and Accelerating Strategic Clinical Trials), are also contributing to these targets.

Progress toward the EU clinical trials targets will be reviewed annually by the ACT EU governance

☞ **Further information**

EMA **European Medicines Agency**

PRIME: new tools added

Launched in 2016, the PRIority MEdicines (PRIME) scheme is based on early dialogue with developers of medicines that have the potential to significantly address patients' unmet medical needs. The aim is to optimize development plans and speed up evaluation of such medicines.

In March of this year, after completion of a two-year pilot, EMA launched three new features for PRIME:

- the regulatory roadmap and product development tracker: to help chart a medicine's progress and flag potential issues early, making it easier for developers and EMA to stay aligned throughout development

Eligibility for PRIME

Any sponsor engaged in an exploratory clinical trial phase of development can submit a request to enter the PRIME scheme, based on the availability of preliminary clinical evidence in patients indicating the promising activity of the medicinal product and its potential to significantly address an unmet medical need (proof of concept).

Applicants from the academic sector and micro-, small-and medium-sized enterprises may submit an eligibility request at an earlier stage of development if compelling nonclinical data in a relevant model provide early evidence of potentially promising activity (proof of principle) and first-in-man studies indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability.

- expedited scientific advice: a fast-track route for developers to receive timely regulatory input on issues critical to the development process
- the submission readiness meeting: a dedicated check-in, about a year before submission, at which EMA and developers discuss the progress of the programme against the plan and identify any remaining evidence gaps to ensure that a comprehensive data package is available for a thorough evaluation by the Committee for Medicines for Human Use.

☞ **Further information**

Integrating RWE into regulatory decision-making

This fourth annual report — covering 8 February 2025 to 7 February 2026 — outlines the progress made in integrating real-world evidence (RWE) into regulatory decision-making, aligned with the European Medicines Regulatory Network (EMRN) strategy to 2028 and in anticipation of the provisions from the new pharmaceutical legislation. EMA coordinates two RWE generation pathways: the Data Analysis and Real-World Interrogation Network DARWIN EU® and studies commissioned via framework contracts.

A total of 108 research topics were assessed, with 48 new topics identified. The vast majority (88%) were addressed through DARWIN EU®, highlighting the increased capability and capacity of this pathway. Feasibility assessments showed a high success rate, with 77% of assessed topics deemed feasible, resulting in 43 completed and 45 ongoing studies by February 2026, representing a 49% increase compared with the previous year.

Research focused primarily on drug utilization, disease epidemiology, medicines safety and studies addressing the design and feasibility of planned studies, a category which increased considerably in the period.

Significant expansion and consolidation of DARWIN EU® were observed: the network increased to 40 data partners across 18 European countries, covering over 250 million patients.

During the reporting period, a survey to investigate the value of the evidence generated was conducted among study requesters: 30% of respondents reported direct use of RWE in formal regulatory decisions, while others highlighted its value for preparedness, methodological learning, and future decision-making.

Overall, the report confirms that regulator-led RWE generation through DARWIN EU® is impactful, scalable, and strategically aligned with EU regulatory priorities. However, continued efforts to enhance data harmonization, quality and interpretability are called for to maximize its potential.

☞ **Further information**

Updated NDSG workplan

The Heads of Medicines Agencies/EMA Network Data Steering Group (NDSG) has published its updated workplan, setting out how data and AI will drive regulatory innovation. The workplan strengthens the use of data standards, sets out a roadmap for AI delivery, advances real world evidence through the Data Analysis and Real-World Interrogation Network DARWIN EU®, and prepares the network for the European Health Data Space and new pharmaceutical legislation. It is organized in six workstreams:

- strategy and governance
- data analytics
- artificial intelligence
- data interoperability
- stakeholder engagement and change management
- guidance and international initiatives.

The first NDSG workplan was adopted in March 2025. The updated workplan constitutes the first annual revision.

☞ **Further information**

Strengthen use of real-world data in EU regulatory decision-making

The final version of the *Data Quality Framework for EU Medicines regulation: Application to Real-world Data (RW DQF)* has now been published. Building on the 2023 Data Quality Framework, the RW DQF provides recommendations and practical guidance for assessing the quality of real-world data underpinning real world evidence in regulatory assessments.

☞ **Further information**

Breakthrough medical devices pilot

EMA has launched a pilot programme to support the development of breakthrough medical devices in the European Union (EU). The aim is to test a new regulatory pathway that supports patient access to highly innovative technologies, while maintaining the EU's rigorous safety and performance standards.

As part of the pilot, manufacturers whose devices are granted 'breakthrough' status will benefit from enhanced regulatory support, including priority scientific advice from the medical device expert panels that are overseen by EMA.

Highly innovative medical devices that demonstrate potential to address unmet medical needs, or that offer substantial advantages over existing technologies, will be eligible for designation as breakthrough.

The pilot will be conducted in three phases. Phase one is open to class III (high risk) medical devices and class IIb active medical devices intended to administer or remove medicines from the body. Subsequent phases of the pilot will be open to other types of devices, including in vitro diagnostics.

☞ **Further information**

EMA, AMA and African regulatory authorities unite on Ebola response

EMA's Emergency Task Force (ETF) is engaging with the African Medicines Agency (AMA) and its

national regulatory authorities (NRAs), and leveraging expertise from the WHO-AFRO African Vaccines Regulatory Forum, to discuss possible clinical trial designs and medical countermeasures to be investigated in the ongoing Ebola outbreak in the Democratic Republic of the Congo and Uganda, caused by the Bundibugyo virus.

This is the first public health emergency whereby EMA is collaborating with AMA, alongside participating African NRAs. Intended to support efficient, coordinated and timely regulatory responses to the outbreak, this engagement is grounded in the ongoing scientific collaboration between EMA and AMA and builds on the extensive experience gained through African regulatory collaboration during previous Ebola outbreaks.

☞ **Further information**

ICH International Council for Harmonisation of Requirements for Pharmaceuticals for Human Use

Updated and expanded Q9(R1) Quality Risk Management Briefing Pack

This new briefing pack contributes to a body of training materials that helps stakeholders understand and apply the principles and guidance set out in the ICH Q9(R1) (Quality risk management (QRM)) Guideline that was finalized in 2023.

Combined, ICH Q9(R1), ICH Q8(R2) (Pharmaceutical development) and ICH Q10 (Pharmaceutical quality system) encourage the further development of science- and risk-based approaches to quality.

The training materials on implementation of the three guidelines illustrate how the guidelines work together as part of a lifecycle framework for an effective pharmaceutical quality system.

☞ **Further information**

Training Module for ICH Guideline M15

ICH has issued a training module for harmonized *Guideline ICH M15: General Principles for Model-Informed Drug Development (MIDD)*. The Guideline covers general principles and good practices for the use of model-informed drug development (MIDD) and harmonises expectations regarding documentation standards, model development, data used in the analysis, and model assessment and its applications.

The new training module gives an overview of the Guideline, covering its key principles, objectives and scope, as well as the key sections of the Guideline: the framework for assessment of MIDD evidence, model evaluation, and MIDD reporting and submission.

☞ **ICH M15 Guideline and associated documents**

MCAZ Medicines Control Authority of Zimbabwe

Commitment to integrity pledge

MCAZ held an Integrity Pledge Signing Ceremony on 22 May 2026. Administered by the Zimbabwe Anti-Corruption Commission, the initiative reinforces MCAZ's institutional commitment to integrity as one of its core values and a key regulatory practice, essential for building and maintaining a robust, credible, and trusted regulatory system. During the ceremony, staff and management formally committed themselves to ethical conduct, accountability, transparency and professionalism in public service.

By embedding integrity into organizational culture and operations, MCAZ seeks to continue strengthening of its governance systems and to uphold its mandate of protecting and promoting public health through the regulation of medicines and medical devices in Zimbabwe.

☞ **Further information**

MHRA Medicines and Health care products Regulatory Agency

Framework for rare disease therapies

MHRA has launched a landmark public consultation — open until 30 July 2026 — on a proposed new regulatory framework that will lead development of rare disease treatments in the UK. The framework sets out a new model for how rare disease therapies for individuals could be tested, licensed and monitored, aiming to speed up and reduce the costs of safe development of therapies for rare diseases, currently affecting 3.5 million people in the UK.

Instead of requiring developers to meet standards designed for large-population diseases, the new framework would introduce a flexible, risk-proportionate framework that acknowledges the realities of rare disease development, while protecting patient safety. Entry to the proposed new pathway would be guided by criteria such as the severity of the disease and unmet need.

A new investigational marketing authorisation would combine clinical trial approval with a progressive route to market authorisation approval. This means that where there is limited evidence, patients could gain access to innovative treatments earlier, subject to approval by the National Institute for Health and Care Excellence on use by the National Health Service.

☞ **Further information; respond to the consultation**

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

Calls for comments

U.S. FDA has issued a draft document entitled *Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing; Draft Guidance for Industry*. It provides recommendations for next-generation sequencing-based methods used in nonclinical studies that will likely be needed to support initiation of clinical trials of investigational human genome editing products. Electronic or written comments on the draft guidance can be submitted until 14 July 2026.

U.S. FDA would also welcome comments on its planned future public workshop series on rare disease innovation, science and exploration. The workshops will focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The emphasis will be on cross-cutting or common issues. Comments highlighting general rare disease-related issues of potential interest for the FDA Rare Disease Innovation Hub will be welcome.

☞ **To submit comments on the draft guidance**

☞ **To submit comments on the workshops**

CIRS — Centre for Innovation in Regulatory Science

Innovative medicines approved in China

In China, recent regulatory reforms have contributed to more efficient drug approval processes, alongside more dynamic approaches to reimbursement decision making. The introduction and wider use of expedited pathways, such as priority review, conditional approval, and breakthrough designation by the National Medical Products Administration, have supported faster approval of medicines addressing unmet medical needs. At the same time, greater emphasis is being placed on evidence requirements and value assessment to inform reimbursement decisions, supported by an annual reimbursement cycle.

The latest CIRS R&D Briefing (104) focuses on approvals for Class 1 innovative medicines approved in China between 2022 and 2024. These medicines are defined as products not previously approved in China or overseas at the time of submission.

The briefing highlights China's evolving role in global pharmaceutical innovation, including the growing contribution of domestic innovation and the increasing importance of China in global development strategies.

Key insights include:

- Class 1 innovative medicine approvals more than doubled from 2022 to 2024: from 23 to 48.
- Class 1 approvals were driven largely by domestic companies: 79 (vs 17 by multi-national companies).
- Use of expedited pathways increased over time, with priority review more common among multinational companies and conditional approval more frequently used by domestic companies.
- 66% of approved Class 1 medicines were included in China's National Reimbursement Drug List, with a median time of 360 days from regulatory approval to reimbursement.

☞ **CIRS R&D Briefing 104: Class 1 Innovative Medicines Approved in China (2022–2024): An International Comparison**

EUREC — European Network of Research Ethics Committees
CPME — Comité Permanent des Médecins Européens (Standing Committee of European Doctors)
CIOMS — Council for International Organizations of Medical Sciences

Joint statement: EC Biotech Act Proposal

The EC's proposal for the European Biotech Act was published on 15 December 2025 and is open for further feedback, with the consultation period being extended on a rolling basis until the Proposal is available in all official EU languages.

The European Network of Research Ethics Committees (EUREC), the Standing Committee of European Doctors (CPME) and CIOMS welcome the Biotech Act Proposal as an important initiative

to strengthen Europe's clinical research ecosystem, improve clinical trial authorization and conduct, and reinforce preparedness for future public health emergencies. Each of these objectives is aligned with World Health Assembly Resolution WHA75.8 on strengthening clinical trials to provide high-quality evidence and improve research quality and coordination.

Together, CIOMS, EUREC and CPME represent recognized expertise in research ethics, medical professionalism, ethical governance, and the protection of research participants and patients. While their mandates differ, they share a commitment to safeguarding the rights, dignity, safety and well-being of clinical trial participants, and to ensuring that clinical research generates high-quality evidence for future patients and public health.

In this context, the three organizations support the Biotech Act Proposal and its ambition to strengthen Europe's clinical research framework. In particular, they welcome its push to strengthen the role of research ethics committees and improve coordination between national competent authorities and ethics bodies, and its emphasis on responsible inclusion and high ethical standards, in line with the World Medical Association's Declaration of Helsinki (2024), the CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016), and the International Council for Harmonisation Good Clinical Practice Guideline (ICH-GCP(R3)) (2025).

Nevertheless, they consider that important gaps remain and in a Joint Position Statement set out recommendations and proposed amendments to the Biotech Act.

In brief, the Biotech Act both represents an opportunity for Europe to regain leadership in innovation, and a demonstration that scientific excellence and high ethical standards are indissociable.

☞ **Submit feedback on the Biotech Act Proposal under "Commission adoption"**

ICLAS **International Council for Animals in Science**

Performance standards for care, use and ethical oversight of animals in science

CIOMS, and ten global and regional science organizations, councils and federations of laboratory animal science associations, have agreed to collaborate with the International Council for Laboratory Animal Science (ICLAS) on the ICLAS Global Harmonization Initiative for Animals in Science.

Why now?

Legislation, guidelines and codes — including several international documents — for research animal care, use and oversight exist in all regions. Globally, however, there is great variation in the aspects covered, when they were produced, and how well they are followed. Moreover, some of the main texts used widely as references are becoming out of date.

Initiative goal and objective

The goal of ICLAS's harmonization initiative is to achieve consensus on outcome-based standards for key factors impacting animal health and well-being, and scientific integrity. Examples of such standards include: meeting the behavioural needs of animals; veterinary care; humane endpoints; effective ethical review; appropriate experimental design and reporting; implementation of the 3Rs (replacement, reduction and refinement); training and competency for animal care and research staff; and promoting a good culture of care within research institutions.

The objective is to produce a document outlining high-level globally harmonized performance (outcome-based) standards for the care, use and ethical oversight of animals in science, to support quality science and promote animal well-being. The proposed standards are not intended to substitute for relevant local and national legislative and regulatory requirements, but rather to serve as guidance. The target date for their completion is early 2028. They will be freely available on the ICLAS website and updated regularly.

An ICLAS Special Working Group on Global Harmonization (SWGGH) is establishing a Drafting Committee. Members will represent partnering organizations, and appropriate geographical balance and disciplinary representation will be assured. Thereafter, the Drafting Committee will propose

Founded in 1956, under the auspices of CIOMS, UNESCO and the International Union of Biological Sciences, ICLAS is a scientific organization dedicated to advancing human and animal health by promoting the ethical care and use of animals in research worldwide.

ICLAS and CIOMS jointly published the International Guiding Principles for Biomedical Research Involving Animals (1985, updated 2012). The Principles remain an important document, but the new standards being developed will build upon, significantly expand and modernize them.

ICLAS continues to be highly relevant given that modern animal research ethics are increasingly international, multidisciplinary, and tied to reproducibility and alternative methods.

specialists and experts from their organizations and networks, to form Working Groups of 4–6 individuals per topic, subject to final approval by the ICLAS SWGGH.

The Working Groups will draft content for each section of the standards, which will be reviewed and agreed upon by the Drafting Committee, and then submitted to the ICLAS SWGGH for final approval. The drafts will be shared widely with other relevant organizations and interest groups — including representatives of publishers of scientific journals and the pharmaceutical sector — for feedback. Feedback will also be sought from specialty groups within laboratory animal science. These would include, for example, organizations representing specific categories such as wildlife or nonhuman primates, and across different fields of research such as pharmacology, physiology, neuroscience and toxicology.

The standards will likely focus on 8–12 areas. Their scope and final number will be agreed between the ICLAS SWGGH and the Drafting Committee.

☞ **Questions about this initiative can be sent via: https://iclas.org/contact**

ILO International Labour Organization

Governance: Hard to build, easy to erode

This new report from ILO finds that more than half of the world's economies face governance conditions that create uncertainty for business and investment.

Produced by the ILO Bureau for Employers' Activities, the report analyses governance trends across 208 economies between 1996 and 2024. It shows that, despite ongoing reform efforts, overall performance has changed little over time, with uneven progress across countries and regions. Indeed, governance gains are fragile and declines more common than progress. Nearly one-third of top-performing countries saw their ranking fall.

Political governance – including accountability, stability, and checks on executive power – emerged as the most vulnerable dimension.

The report notes that the message for reformers is that governance gains must be actively defended. They and cannot be taken for granted.

☞ **ILO report: Governance: Hard to build, easy to erode**

PAHO Pan American Health Organization

Clinical Trial Accelerator launched

Launched by PAHO in April 2026, the Clinical Trials Accelerator is designed to strengthen regional networks and partnerships, support the development of more robust, multi-country clinical trials, and reinforce national research systems that are aligned with international ethical and regulatory standards.

The Accelerator builds on lessons learned from the COVID-19 pandemic, which underscored both the importance of timely, coordinated research and the gaps in the Region's capacity to generate high-quality evidence at scale.

Following a 2023 PAHO regional workshop on clinical trials, countries and partners identified concrete actions to improve coordination, expand research capacity, and promote more collaborative, multi-country studies across the Americas.

One of the actions is the harmonization of clinical trial agreements, which can help reduce delays and facilitate collaboration. Currently, country-by-country negotiation of clinical trial agreements (CTAs), insurance requirements and site contracts can be very time consuming.

Standardized CTAs could shave weeks from study startup. PAHO is now building the institutional infrastructure to make that happen.

☞ **See also Portal of Clinical Trials of the Americas**

WHO World Health Organization

Kazakhstan: 1st Central Asian country to reach maturity level (ML) 3

Kazakhstan has become the first country in Central Asia to reach Maturity Level 3 (ML3) for the regulation of medicines and imported vaccines under WHO's Global Benchmarking Tool. This designation recognizes that the country has a stable, well-functioning and integrated regulatory system for medicines and imported vaccines that meets international standards.

Regulatory authorities operating at ML4, the highest level in WHO's GBT classification, may be eligible for designation as WHO Listed Authorities, subject to additional performance assessments, enabling them to play a more prominent role as a trusted regulatory authority of reference.

☞ **Further information**

Application period open: 2027 update of WHO Model Lists of Essential Medicines

The WHO Model Lists of Essential Medicines (EML) and Essential Medicines for Children (EMLc) are reviewed and updated every two years by the WHO Expert Committee on Selection and Use of Essential Medicines. The process relies on an evidence-based assessment of effectiveness and safety, as well as additional factors such as the burden of disease, resource use and feasibility.

Applications for inclusion in the Lists can now be submitted. The deadline for submissions is 6 November 2026.

Revision and updating of the lists will be carried out at the 26th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines, scheduled from 3 to 7 May 2027.

☞ **Further information**

Good practices in clinical trials: new WHO online course

WHO has launched a new free online course, *WHO Good Practices for Clinical Trial Design and Implementation*. Available on the WHO Academy online learning platform, this self-paced course translates the *WHO Guidance for Best Practices for Clinical Trials* into practical, applied learning for those involved in clinical trials.

Structured around five universally applicable scientific and ethical principles, it explores how these principles can be applied in different settings, disease areas and health systems. The course emphasizes real-world decision-making, addressing common challenges in trial design, conduct and oversight, including participant protection, ethical review, community engagement, operational feasibility and relevance to public health needs. It takes about 4.5 hours to complete.

In making this course freely available online, WHO is seeking to reduce barriers to high-quality clinical trials education, and support countries in building sustainable research capacity aligned with national and global health priorities.

☞ **Register for the course here**

World Health Assembly Resolution on Pharmacovigilance

In May 2026, the Seventy-ninth World Health Assembly adopted a resolution to advance smart and efficient pharmacovigilance as a core element of strong and resilient health systems, marking a significant step towards expanding access to safe and effective medicines and vaccines worldwide.

The resolution calls on Member States to strengthen and integrate systems for monitoring the safety of medicines, vaccines and other health technologies, while improving regulatory capacity and workforce development. It also encourages the use of digital tools and real-world data to enhance safety surveillance.

Emphasizing lessons from recent health emergencies, the resolution highlights the importance of timely detection of safety signals, effective risk communication and efforts to counter disinformation and misinformation.

The first WHO Resolution on pharmaco-vigilance (16.36) was adopted in 1963, during the 16th World Health Assembly and led to the formation of the WHO Programme for International Drug Monitoring.

☞ **Further information**

CIOMS Secretariat news

Dr Otmar Kloiber retires from World Medical Association

It is with some sadness that we announce the retirement of Dr Otmar Kloiber from the World Medical Association (WMA) and, consequently, his departure as the WMA representative on the CIOMS Executive Committee. Otmar served as WMA Secretary General from 2005 and as a member of the CIOMS Executive Committee from 2010.

However, Otmar's unique contribution to medical ethics and human rights in healthcare at the international level started long before his involvement with either WMA or CIOMS. He joined the German Medical Association in 1991 — serving first as foreign relations adviser, then as Deputy Secretary General, then as Secretary-General — and quickly established his international network of expertise. He began collaborating with CIOMS in the late 1990s. At this time, WMA was revising its Declaration of Helsinki and CIOMS its International Ethical Guidelines for Health-related Research involving Humans (IEG). It was my privilege to meet Otmar during this period, while I was collaborating with Dr Juhana Idänpään-Heikkila (CIOMS Secretary-General) and Sev Fluss (CIOMS Special Adviser).

Over the past 25 years our paths crossed frequently, and on every occasion, I was struck by Otmar's intellectual rigour and unwavering commitment to defending the principles of medical ethics. Beyond his encyclopaedic understanding of the issues at stake, he has been a skilled and effective bioethics diplomat, building bridges across cultures, disciplines and professions. His contribution to the development of the principal international ethical guidelines that continue to guide medical research in our

Tributes from fellow CIOMS Executive Committee members

"Otmar was a great support in creating a very productive collaboration between our two organizations. When writing the 2016 CIOMS ethics guidance and the 2024 version of the Declaration of Helsinki, we managed to bring the two documents much closer together, helping to create an environment in which ethical clinical research can flourish."

Professor Johannes JM van Delden
Former president of CIOMS

"I came to appreciate Otmar's experience, his measured judgement, and his consistent commitment to thoughtful and balanced discussions, particularly on complex ethical matters. He contributed in a very meaningful way to strengthening the relationship between CIOMS and the World Medical Association, with a clear focus on advancing medical ethics at the global level. His role in the 2024 revision of the Declaration of Helsinki reflected this longstanding engagement."

Professor Hervé Le Louët
Immediate past president of CIOMS

"I would like to express my heartfelt thanks to Otmar for his outstanding leadership. His work has strengthened global medical ethics and advanced the profession's mission. His collaboration with non-profit organizations has been invaluable in creating lasting frameworks for ethical research, patient protection and international cooperation. I wholeheartedly honour his wisdom and his enduring contribution to advancing ethics in medicine and research worldwide."

Dr Varvara (Barbara) Baroutsou
Former President of International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine

increasingly complex world has been immense, grounded as it is in profound knowledge of the history and theories of medical ethics and understanding of the relevant legal issues.

Throughout his career, Otmar has played a vital role in defending and promoting the highest ethical and professional standards to safeguard patients, research participants and populations. Tirelessly and without fail, Otmar has stood up to defend those principles whenever they were challenged, underscoring for his listeners — sometimes in forceful terms — the importance of upholding the foundational values of humanity, and especially with respect to the most vulnerable.

As a member of the CIOMS Executive Committee, Otmar contributed actively to its discussions and work. His insights were invariably thoughtful and highly valued. His experience, judgement and commitment to advancing medical ethics strengthened our deliberations and supported numerous important initiatives. CIOMS especially appreciated his role in ensuring that the 2024 revision of the Declaration of Helsinki incorporated perspectives from CIOMS, resulting in even closer alignment between the Declaration and the CIOMS IEG.

On behalf of CIOMS, I would like to express our sincere appreciation for Otmar's longstanding engagement and collegiality, and the wisdom he brought to this organization. We are deeply grateful for his dedication and for the partnership he fostered between our organizations over many years. We wish him a fulfilling, rewarding and well-deserved retirement.

Professor Dominique Sprumont
Vice-President
CIOMS

CIOMS General Assembly 2026

On 16 June 2026, Dr Stella Blackburn, President of CIOMS, opened the CIOMS 2026 General Assembly. Referring to current political instability and the "attack on science from all sides", she emphasized that 2025 had nevertheless been a highly successful year for CIOMS. She congratulated Dr Otmar Kloiber on his retirement and welcomed Dr Samvel Azatyan, who has served as Senior Adviser to CIOMS since September 2025.

Dr Lembit Rägo reviewed CIOMS activities for 2025, highlighting the publication of two major reports and the launch of two new Working Groups (WGs). CIOMS and its outputs continued to be cited in journals, books and reports, with research ethics remaining its most referenced area. Webinars contributed further to the organization's visibility and impact, while attendee surveys provided feedback to help determine how future webinar content and delivery could be optimized. Participation in major scientific, regulatory and ethics fora also supported dissemination of new CIOMS guidance, often through presentations by WG members themselves.

Website traffic and subscriber numbers continued to grow across a broad range of sectors, reflecting sustained interest in CIOMS guidance and recommendations among diverse stake-holders.

Looking ahead, Dr Rägo noted that two new WG reports are expected before the end of 2026.

New Executive Committee member

Dr Parsa-Parsi was confirmed as the new Executive Committee member representing the World Medical Association, following the retirement of Dr Otmar Kloiber. A physician with a Master of Public Health, he brings extensive experience in global health, medical ethics, and international medical leadership. His career spans senior roles in national medical associations, governmental and multilateral institutions, and academia.

Above: Dr Ramin Walter Parsa-Parsi, MD, MPH, assumed the position of Secretary General of the World Medical Association, as of 1 May 2026, succeeding Dr Otmar Kloiber

IFMSA Annual Visit to CIOMS

The International Federation of Medical Students' Associations represents 1.5 million medical students worldwide. Every year, it hosts a Youth Pre World Health Assembly, including sessions on global health topics, interactive workshops and discussions on major health issues, in the days preceding the World Health Assembly. In addition, IFMSA members visit CIOMS to hear about the latter's mandate and current activities, and to discuss global health challenges. This year's visit took place on 19 May 2026.

CIOMS values IFMSA because it combines youth leadership, global representation, medical education, ethics and public health advocacy, all of which are important if healthcare is to be adapted to meet future challenges.

Left to right: Dr Samvel Azatyan (Senior Adviser, CIOMS); Alfred Edwar (Egypt); Dr Lembit Rägo (Secretary-General, CIOMS); Lotti Holste (Germany); Edna Adu (UK); Anna Liakopoulou (Greece).

☞ **IFMSA participation in World Health Assembly**

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Top ten CIOMS publication downloads 1 April – 30 June 2026

2026	Glossary of ICH Terms and Definitions (Version 10)	1044
2025	Artificial intelligence in pharmacovigilance	1026
2025	CIOMS Cumulative Glossary, version 4 [a]	554
2025	Benefit–risk balance for medicinal products (English, 2025 + Chinese, 2026)	361
2016	International ethical guidelines for health-related research involving humans [b]	247
2005	Management of safety information from clinical trials [c]	133
2025	Severe cutaneous adverse reactions (SCAR)	112
2024	Practical Aspects of Signal Detection in Pharmacovigilance	111
2024	Real-world data and real-world evidence in regulatory decision making [c]	108
2020	Drug-induced liver injury (DILI)	102

[a] CIOMS Cumulative Glossary with a Focus on Pharmacovigilance

[b] Also available in: Arabic, Chinese, French, Japanese, Korean, Polish, Portuguese, Russian, Spanish, Ukrainian

[c] Also available in Chinese

[d] Drug-induced liver injury (DILI): Current status and future directions for drug development and the post-market setting

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