



In this newsletter

Just published

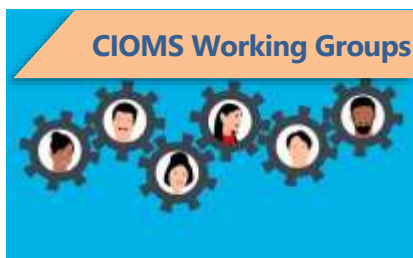


Updated training module: CIOMS International Ethical Guidelines for Health-related Research Involving Humans

WHO-ISoP Pharmacovigilance Curriculum: 2026 Update

Artificial intelligence in pharmacovigilance: *Drug Safety* article

CIOMS Working Groups



Working Group XVII: Long-term Safety of Medicines

Working Group XVI: Development Safety Update Report

CIOMS@ international events



Events: CIOMS at DIA Latin America Annual Meeting, ECPM Seminar & 25th ISOP Global Annual Meeting **Save the date:** 2nd CIOMS webinar on the microbiome; FDA-Reagan Udall Foundation hybrid meeting on the patient voice; DIA-MEB excellence in pharmacovigilance; DIA Japan; DIA Middle East and Africa, EMA CTIS training programme; European Pharmacovigilance Congress; HMA-EMA forum on Eudravigilance; ISOP seminar on AI in pharmacovigilance

News roundup



Regulatory news roundup

ACT EU; ANVISA/INVIMA; EMA; HSA; ICH; NMPA; U.S. FDA

Other related news

CIRS; EFPIA; Global Self-Care Federation; WHO

CIOMS Secretariat news



Student award 2026

CIOMS cited

Top ten CIOMS publications

Just published

Navigating the 2016 International Ethical Guidelines

Updated CIOMS training module

Progress towards a world where all can enjoy optimal health and health care is critically dependent on all kinds of medical research involving humans. Researchers, sponsors, research ethics committees and health authorities involved in such research have a moral obligation to ensure that it upholds human rights, and respects, protects, and is fair to study participants and any communities where the research is conducted. This obligation is enshrined in the Declaration of Helsinki (DoH). Originally developed and adopted by the World Medical Association (WMA) in 1964 (and amended thereafter), the DoH provides a succinct statement of ethical principles for medical research involving human participants, including research on identifiable human material and data. It is widely regarded as the cornerstone document on human research ethics.

The CIOMS *2016 International Ethical Guidelines for Health-related Research Involving Humans* (IEG), prepared in collaboration with the World Health Organization, provide detailed background information for the DoH principles and guidance on their implementation. In addition, CIOMS developed an online training module that enables users to deepen their understanding of the CIOMS guidance and how they apply it in their own research.

In October 2024 — in response to recent shifts in medical research ethics, and to new harms and risks now being generated in the medical research domain — WMA issued its *10th revision of the DoH*. This revision seeks to strengthen commitment to fairness and equity in research, calls for increased protection for vulnerable participant populations and improved transparency in clinical trials, and has expanded the scope of application of the Declaration to all individuals, teams and organizations involved in medical research. The DoH and the 2016 IEG are now more closely aligned. Indeed, the latter, as well as the *CIOMS 2022 report and recommend-*

ations on patient involvement in the development, regulation and safe use of medicines, with their emphasis on ethical reasons for patient involvement in these activities, can be considered to have anticipated the need for the latest revisions to the DoH.



Given the revision of the DoH, the CIOMS IEG training module has also been revised, in particular to help users to understand the position of CIOMS on specific issues, such as the use of placebo or the level of acceptable risk. The modules now include six cases: biobanking; disaster research; social value; waiver of informed consent; teenagers and sexual health; and AI research. Participants are invited to reflect on and identify which paragraphs in the CIOMS IEG would be applicable to each case.

In view of increasing geopolitical instability, weakening trust in multilateral institutions, and ongoing challenges to fundamental human rights, it is more important than ever that medical researchers commit to good ethical practices. Combining scientific rigour with adherence to the declaration's principles is a must.

 **The CIOMS training course on the CIOMS International Ethical Guidelines is free of charge and can be accessed [here](#). Following successful completion of the course, users will receive a certificate.**

WHO-ISoP Pharmacovigilance Curriculum: 2026 Update

Responding to developments that have reshaped pharmacovigilance

A special article in *Drug Safety* authored by Beckman et al., provides an overview of the expanded update to the pharmacovigilance curriculum developed jointly by the World Health Organization (WHO) and the International Society of Pharmacovigilance (ISoP), originally issued in 2014.

Key developments that led to the update

Therapeutic innovations have accelerated
Global health emergencies and an evolving risk landscape
Digital transformation and data science have reshaped healthcare and pharmacovigilance practice
Health behaviour and communication have changed fundamentally
Environmental and societal considerations are increasingly important to pharmacovigilance

The update responds to scientific, technological, regulatory, social, and public health developments that have reshaped pharmacovigilance over the last 12 years. These developments require well-trained pharmacovigilance professionals who can identify, assess, interpret, communicate and mitigate risks using robust, data-based methods, and take evidence and

uncertainty into account when making decisions. The developments also require structured educational guidance to help trainers design courses that are current, relevant and adaptable to different audiences and settings.

The overview describes the process of updating which included a much greater and more diverse range of contributors — from 18 to 82. It highlights that a major strength of the updated course lies in its broad and multidisciplinary foundation, developed collaboratively by experts from academia, regulators, industry, nongovernmental organizations and consultant entrepreneurs from across the world. It has also benefited from the joint expertise of WHO (including its advisory groups and collaborating centres) and ISoP, and reflects their extensive experience and cooperation in supporting pharmacovigilance capacity building in countries with diverse healthcare systems, resources and levels of industrialisation.

The curriculum is included in the overview article, which also provides links to its supplementary electronic materials.

 [Drug Safety overview: ISoP Pharmacovigilance Curriculum: 2026 Update](#)

Artificial Intelligence in Pharmacovigilance

Guiding Principles from CIOMS Working Group XIV published in *Drug Safety*



A newly published article in *Drug Safety* provides an overview of the CIOMS Working Group XIV report: *Artificial Intelligence in Pharmacovigilance* and illustrates how its seven guiding principles may be applied in practice.

The article describes development of the report to reflect a broad

international consensus on the responsible development and use of artificial intelligence (AI) in pharmacovigilance. Rather than prescribing specific technologies or methodological approaches, it focuses on principles designed to remain applicable over time and on supporting stakeholders in developing and deploying AI systems that maintain scientific rigour, transparency and public trust, while at the same time enabling innovation to support the safe use of medicines.

 [Article: CIOMS Working Group XIV report: Artificial Intelligence in Pharmacovigilance](#)

CIOMS Working Group news

Working Group updates

Working Group XVII: Long-term Safety of Medicinal Products met in Geneva on 29 and 30 June 2026. A new WG member with expertise in research ethics was welcomed, reflecting the Group's intention to strengthen ethical perspectives within discussions on long-term safety. The WG refined its definition of long-term safety, agreeing that it should be sufficiently broad to accommodate different medicinal product classes while clearly distinguishing long-term safety from routine pharmacovigilance.

Working Group XVI: Development Safety Update Report (DSUR) held an in-person meeting in Tallinn, on 28 and 29 September 2026, focusing on updates from the subgroups, including on signal detection, management, reference safety information, and evaluation of risks and benefit-risk considerations. The group also discussed evolving pharmacovigilance regulations and their regional implementation.



Members of **CIOMS Working Group XVII: Long-term Safety of Medicinal Products** at their June 2026 meeting.

CIOMS@ international events

In Mexico, Switzerland and Costa Rica

September 2026

Dr Samvel Azatyan, Deputy Secretary-General of CIOMS, participated in a session dedicated to *Navigating the AI Era — Leveraging Artificial Intelligence Across Drug Development, Regulatory Science, and Pharmacovigilance in Latin America* at the DIA Latin America Annual Meeting in Mexico City, 9–11 September 2026. Dr Azatyan presented CIOMS' perspective on: "Artificial Intelligence in Pharmacovigilance: Keeping Patients at the Center in Latin America".

On 10 September 2026, Dr Lembit Rägo, Director-General of CIOMS participated in the ongoing Frontiers in Drug Development series of

the [European Center of Pharmaceutical Medicine](#) in Basel, Switzerland. The seminar focused on advances in pharmacovigilance for ensuring the safety of medicines. Dr Rägo gave an overview of CIOMS activities and reports that are particularly focused on medicines safety.

Dr Rägo also made a virtual presentation – in a session focusing on global updates in pharmacovigilance — on the final day of the 25th Global Meeting of the International Society of Pharmacovigilance (ISoP) that took place in Costa Rica 22–25 September 2026.

Save the date



Second CIOMS webinar on the Reciprocal Effects of Drugs and the Microbiome: 7 October 2026

Microbiome-drug interactions have important implications for medicines efficacy and patient safety, antimicrobial resistance and regulatory decision making, yet they remain under-explored in drug development and safety monitoring. For product developers pharmaceutical companies, contract research organisations and consultants, understanding these emerging interactions will become increasingly relevant to decisions around drug development, clinical development, safety assessment and regulatory strategy. This webinar will provide an overview of the latest evidence and explore what these findings could mean in practice: for product development, safety monitoring and regulatory decision making.

The webinar is free of charge for not-for-profit attendees (such as academics, regulators and health professionals). A fee of 99.00 CHF will be charged to for-profit attendees (such as consultants, contract research organisations, and pharmaceutical companies).

[Programme details and registration are available here](#)



Left to right: Experts and panellists who will participate 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 Räägo (Secretary-General, CIOMS); Dr Oliver Aasmets (University of Tartu, Estonia); Dr Kertu Liis Krigul (Research Fellow of Microbial Communities, Institute of Genomics, Estonian Genome Centre).



The Patient Voice in Rare Disease Medical Product Development, hybrid meeting, 16 October 2026

FDA in partnership with the Reagan-Udall Foundation for the FDA is convening a hybrid meeting exploring the patient voice in rare disease medical product development, in person at FDA White Oak, Silver Spring, Maryland, USA or online via Zoom. The target audience is patients and patient advocates in the rare disease community, alongside regulatory affairs, clinical and product development professionals working on rare disease programmes who want to understand how patient input is gathered and used across the development timeline.

[Programme information and registration](#)



Medicines Evaluation Board

DIA/MEB Excellence in Pharmacovigilance: GVP Modules I to XVI, Amsterdam, The Netherlands: 13–16 October 2026

This intermediate-level face-to-face course in Amsterdam, delivered by DIA in collaboration with the Dutch Medicines Evaluation Board, will combine lectures, exercises, and extensive interaction with trainers and peers. The programme covers all major pharmacovigilance processes outlined in Good Pharmacovigilance Practice Modules I to XVI, including Individual Case Safety Reports, signal management, risk management,

quality management systems, and the latest updates on pharmacovigilance legislation and ICH activities.

 [Programme information and registration](#)



23rd DIA Japan Annual Meeting 2026: Crossing Boundaries, Shaping a Future Beyond Imagination with Innovation, Tokyo, Japan: 18–20 October 2026

The 23rd DIA Japan Annual Meeting will provide a forum where participants from diverse fields, roles, organizations, and countries can come together to explore possibilities beyond imagination through “innovation” born of interdisciplinary collaboration.

 [Programme information and registration](#)



Middle East & Africa Conference, Abu Dhabi, United Arab Emirates: 18–20 October 2026

The DIA Middle East & Africa Conference 2026 marks a new phase of regional collaboration, bringing together key stakeholders from across the Middle East and Africa, to facilitate meaningful dialogue and the development of practical solutions to shared regulatory, scientific and healthcare innovation challenges.

 [Programme information and registration](#)



EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINES. HEALTH.

CTIS System Sponsor end user training programme, online: 19–22 October 2026

EMA is offering a virtual training programme, organised by DIA, to support sponsor user preparedness concerning the new process for submitting clinical trial applications in the European Economic Area via the Clinical Trials Information System and in compliance with the European Union Clinical Trials Regulation.

 [Programme information and registration](#)



European Pharmacovigilance Congress 2026, online: 18 & 19 November 2026 in person, Milan, Italy: 3 & 4 December 2026

Organized by the Pharma Education Center, this congress brings together pharmacovigilance professionals at all career levels, to discuss and learn about the evolving pharmacovigilance world and its new trends, and effective pharmacovigilance strategies and tools. CIOMS' Director-General, Dr Lembit Rägo, will introduce a virtual session on 19 November 2026 focused on the impact of new regulations and guidelines on pharmacovigilance operations. He will also describe CIOMS's latest activities aimed at promoting and supporting pharmacovigilance.

 [Programme information and registration](#)



EUROPEAN MEDICINES AGENCY
SCIENCE. MEDICINES. HEALTH.

Second HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection: online, 1 & 2 December 2026

The Heads of Medicines Agencies (HMA) and EMA will host this second HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection to: mark the 25th anniversary of EudraVigilance and reflect on its critical role in safeguarding public health; inform stakeholders about ongoing and forthcoming relevant developments in international guidance, signal management updates, and use of real-world evidence; and further foster stakeholder engagement and collaboration.

 [Programme information and registration](#)



10th ISoP Seminar: Intelligent Automation in Pharmacovigilance, Boston, Cambridge, USA: 3 & 4 December 2026

Through scientific exchange, multidisciplinary collaboration and real-world experience, participants will examine how emerging technologies, including artificial intelligence and digital solutions, can strengthen pharmacovigilance while ensuring that innovation remains evidence-based, ethical, transparent, and focused on improving patient safety worldwide.

 [Programme information and registration](#)

Regulatory news roundup

ACT EU

Accelerating Clinical Trials in the European Union

Monitoring the European clinical trials environment: April–June 2026

The metrics in this report provide information on the trend of the clinical research environment in the European Union (EU) and European Economic Area (EEA).

In Q2 2026, an average of 208 new clinical trial applications were submitted per month in the Clinical Trials Information System. The median time from submission to decision for new initial clinical trial applications was 109 days.

At the time when the report was generated, more than 6,725 initial clinical trials were ongoing in EU/EEA under the regime of the Clinical Trials Regulation (EU) No 536/2014. The most commonly investigated therapeutic area is neoplasms (tumours).

 [Clinical trials report](#)

ANVISA

Agência Nacional de Vigilância Sanitária, Brazil

INVIMA

Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Colombia

Cooperation on regulatory reliance

Latin America is experiencing an accelerated push towards regulatory harmonization, whereby health authorities increasingly align technical standards, reliance pathways, evaluation procedures and post-market oversight frameworks.

In July 2026, the Brazilian regulatory authority, ANVISA, and the Colombian regulatory authority INVIMA, signed a cooperation agreement based on regulatory reliance. It will allow each agency to recognize the technical assessments for medicine registration and post-registration conducted by the other authority. The principal objective is to optimise use of resources, reduce bureaucracy and cut approval times for medicines in both countries. The agreement follows the endorsement in March 2026 of the Rio Declaration for Latin America Regulatory Convergence by the regulatory authorities of Chile, Colombia, Cuba, Mexico, Paraguay, Panama, and Brazil.

Further information

EMA

European Medicines Agency

Proposed reflection paper on MMPs

The European Medicines Agency (EMA) has published a concept paper outlining topics to be addressed in a reflection paper on non-clinical development of microbiome-based medicinal products (MMP).

MMPs represent an innovative class of therapeutics originating from microbiomes (human, food-related and/or environmental). They are intended to treat or prevent diseases by modulating the human microbiome, such as immune-mediated disorders, recurrent or treatment-resistant infections, metabolic disorders and selected cancer indications.

Unlike standard pharmaceuticals, MMPs may consist of live or non-living microorganisms or their derivatives. These products can modulate the human microbiome through diverse mechanisms. Their development and evaluation pose unique regulatory and scientific challenges that are insufficiently addressed by existing guidelines, which were primarily designed for standard pharmaceuticals (including biologicals) and advanced therapy medicinal products. The absence of tailored guidance may lead to increased uncertainty for developers, inconsistencies in regulatory submissions and evaluation, and potential delays in product development.

The proposed reflection paper will outline current thinking on the non-clinical development and evaluation of MMPs and support a harmonized approach across the European Union for clinical trials and marketing authorisation. It will make recommendations on emerging issues in view of future developments and changing practices in the field of MMPs.

 [Consultation paper on MPPs](#)

New safety module in CTIS

A new safety module of the Clinical Trials Information System (CTIS) — the EU-wide regulatory IT platform that manages all clinical

trials conducted under the EU Clinical Trials Regulation (Regulation (EU) No 536/2014) — went live on Monday 28 September 2026, to be followed by a two-month transition period ending on 30 November 2026.

The new safety module introduces updated processes for the submission and management of annual safety reports (ASRs). It will reduce administrative burden and provide greater flexibility for sponsors while supporting more harmonised procedures across Member States.

For sponsors this means:

- Ongoing ASRs will continue to be managed and finalised in the current system.
- All new ASRs must be submitted and managed in the new safety module. Submission in the current system will no longer be possible.
- Access to finalised ASRs in the current system will no longer be available after the transition period ends.

 [Safety module instructions](#)

Open consultation: similar biological medicinal products

The Guideline on Similar Biological Medicinal Products (CHMP/437/04 Rev.1) was last revised in 2015. Since then, major progress has been made in the analytical sciences and regulatory field of biosimilars, as indicated by:

- The [reflection paper on a tailored clinical approach in biosimilar development](#) and initiation of the [ICH M18 Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs](#).
- [New EU pharmaceutical legislation](#) which will amend the legal-regulatory definition of a biosimilar.

The Guideline therefore needs to be updated to align it with the changing legal, regulatory and scientific landscape.

The concept paper on revision of the Guideline is available for public consultation and comment until 31 October 2026.

 [Concept paper on revision of the Guideline on Similar Biological Medicinal Products](#)

 [Comments should be provided using this EUSurvey form](#)

EMA 2025 annual report

The report outlines the most important achievements in evaluating and monitoring human and veterinary medicines in Europe during 2025. They include:

- 104 medicines recommended for marketing authorisation, including 38 with new active substances and 16 for treatment of a rare disease
- 3 medicines recommended for marketing authorisation following an accelerated assessment
- 89 extensions of indication were recommended, including 40 for paediatric use
- enhanced development support for six promising medicines that target an unmet medical need
- product information for 432 centrally authorised medicines updated on the basis of new safety data.

The report also highlights successes in accelerating and optimising the assessment of medicines, which included: reaching full implementation of the Clinical Trials Regulation (with all clinical trials in the EU now operating under a single, unified legal framework); addressing medicines shortages; enhancing the use of real-world evidence; and promoting the safe and responsible use of artificial intelligence.

 [Access the full report here](#)

2025 AI Observatory Report

The 2025 AI Observatory report provides an overview of available guidance and policy, applications of artificial intelligence (AI), ongoing collaborations and engagement activities with stakeholders and partners, as well as progress in European Union-funded initiatives and regulatory science research. The report will inform future network engagement and priorities for implementation of EMA's Network Data Steering Group 2026–2028 workplan and the European Medicines Agencies network strategy to 2028.

 [Access the full report here](#)

Real-world evidence in regulatory decisions: new report

EMA regularly reports on the progress made on real-world data (RWD) studies to support regulatory decision making. The latest report

covers the period from 8 February 2025 to 7 February 2026.

As with previous reports, the focus is on real-world evidence (RWE) generation, mostly via two pathways established by the European Medicines Agency (EMA): **DARWIN EU®** and studies commissioned via framework contracts for scientific studies. The report also covers the value of EMA-generated RWE for regulatory decisions, progress made on operational aspects since the last report, as well as methodological advice provided on the use of RWD within regulatory submissions. It highlights how EMA-led RWE generation aligns with the focus areas of the European Medicines Regulatory Network (EMRN) strategy to 2028, by focusing on generating strong scientific evidence, which is incorporated into decision making processes or can inform, for instance, strategies for prevention of medicine shortages or antimicrobial resistance.

In terms of improvement for RWE generation, more data harmonisation, including more consistent coding, shared definitions, and aligned analytical approaches across countries in order to reduce methodological heterogeneity, appear to be needed. Additionally, some inherent clinical heterogeneity arises from different populations, and healthcare systems and should not be corrected but rather considered in interpretation.

 [Access the full report here](#)

HSA

Health Sciences Authority, Singapore

Cooperation on regulatory reliance

HSA has announced new and expanded collaboration with the African Medicines Agency, the Saudi Food and Drug Authority and Malaysia's National Pharmaceutical Regulatory Agency, to pilot use of HSA's medicine assessments. Combined, these initiatives aim to reduce duplicated regulatory work, improve the efficiency of health product evaluations across jurisdictions, and widen the opportunities for regulators in African countries, Malaysia and Saudi Arabia to reference HSA's regulatory work. This will in turn support more timely access to safe and innovative products and strengthen Singapore's biomedical ecosystem and international regulatory leadership.

 [Further information](#)

ICH

International Council for Harmonisation
of Requirements for Pharmaceuticals for Human Use

ICH E6(R3) Annex 2 for GCP published

In June 2026, the ICH Assembly endorsed Annex 2 of the ICH E6(R3) Good Clinical Practice (GCP) Guideline. Annex 2 provides additional GCP considerations tailored to the evolving clinical trial landscape, covering decentralised elements, pragmatic elements and the use of real-world data. It will come into effect on 15 January 2027.

ICH E6(R3) now consists of the Principles, Annex 1 and Annex 2. The Principles and Annex 1 were adopted on 6 January 2025, introducing a flexible, risk-based framework for interventional clinical trials that accommodates a modern approach to the design and conduct of clinical trials. Since Annex 2 builds on the foundations established in the Principles and Annex 1, and is not intended to be read in isolation, all three documents have been consolidated into a single unified ICH E6(R3) guideline.

ICH E6 is one of ICH's three foundational Tier 1 Guidelines and therefore an implementation requirement for any regulatory authority wishing to become an ICH member.

 [ICH E6\(R3\) GCP Guideline](#)

NMPA

National Medical Products Administration, China

15th Five-Year Plan for Pharmaceutical Industry Development

NMPA is a member of the group that has just issued China's 15th Five-Year Plan for Pharmaceutical Industry Development, which sets out the country's pharmaceutical industrial policy for 2026–2030 and signals its resolve to “turn drug innovation into a strategic strength”. The plan outlines targets for keeping biomedical research, development and application at the global forefront by 2030.

By the end of 2025, China had 4,751 innovative drugs in development, representing approximately one-third of the global pipeline and making it world's leading country in terms of drugs under development.

 [Further information](#)

U.S. FDA

U.S. Food and Drug Administration

Master Protocols for Drug and Biological Product Development: revised draft guidance (June 2026)

This revised guidance provides recommendations on the design and analysis of trials conducted under a master protocol. It focuses on randomized trials using a master protocol intended to contribute to evidence of safety and effectiveness of drugs. The document also provides guidance on the submission of master protocol documents for FDA review, additional recommendations on basket trials, and minor changes for clarity on topics such as randomization, choice of control, and informed consent.

🔗 [Access the full guidance here and a summary document here](#)

Advancing innovative alternatives to animal testing

FDA has issued a direct final rule that updates its regulations to clarify that non-animal methods can be used, where appropriate, for testing the safety of drugs and biological products intended for human use, before they are tried in humans.

The update reflects advances in science and technology that have expanded the range of testing options available in human drug development, including methods using human cells, organs-on-chips, computer models and other advanced technologies.

The rule removes language that could suggest that animal testing is the only acceptable way to generate safety information for regulatory decisions relating to products intended for human use. It does not eliminate or prohibit animal studies, change evidentiary standards or impose new costs or requirements on drug developers.

Additionally, to demonstrate their practical application, the FDA also launched a [database featuring specific uses of new approach methodologies \(NAMs\)](#). The initial release includes 25 examples drawn from publicly available FDA review materials. Developers may use NAMs to generate safety information when the methods are adequately validated and appropriate for the product and regulatory issue concerned.

The agency is inviting the public, including clinicians, parents, caregivers, the scientific

community, industry and others, to comment on the rule.

🔗 [Final rule; how to submit a public comment](#)

🔗 [See also: FDA Draft Guidance to Cut Unnecessary Animal Testing for Cancer Drugs](#)

Other related news

CIRS

Centre for Innovation in Regulatory Science

New drug approvals by six major authorities: 2016–2025

Focusing on 2025, R&D Briefing 106 from CIRS presents the results of an analysis of new active substance (NAS) approvals by six major regulatory agencies: the European Medicines Agency (EMA), the US Food and Drug Administration (U.S. FDA), the Japan Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Swissmedic and the Australian Therapeutic Goods Administration (TGA). The analysis also examines trends from 2016 to 2025. Key findings include the following:

- In 2025, FDA approved the highest number of NASs, with 50 approvals, followed by Health Canada (44), TGA (42), PMDA (40), EMA (39) and Swissmedic (34).
- In 2025, the use of expedited review pathways for NAS approvals varied notably across agencies. FDA had the highest proportion at 56%, followed by PMDA (53%), Health Canada (25%), Swissmedic (18%), TGA (10%) and EMA (5%). PMDA's proportion of expedited approvals increased considerably from 34% in 2024 to 53% in 2025.
- The use of facilitated regulatory pathways increased for all authorities during 2021–2025 compared to 2016–2020.
- The NASs approved by all six authorities increased from 37 in 2016–2020 to 52 in 2021–2025.
- While the overall inclusion of patient experience data (PED) in FDA NAS approvals decreased in 2025 to 72% compared with 84% in 2024, levels remain broadly aligned with earlier years. The use of multiple sources of PED - alongside sponsor-submitted data - has increased from 12% in 2021 to 20% in 2025, pointing to a more proactive and

diversified approach to integrating patient evidence. Between 2021 and 2025, anti-infective therapies had the shortest overall median approval time across the six authorities (273 days).

 **CIRS Briefing 106**

EFPIA European Federation of Pharmaceutical Industries and Associations

Assessment of EU's life sciences competitiveness

A new report from EFPIA notes that: "Once a beacon of scientific excellence and a modern powerhouse in pharmaceuticals, Europe now risks further falling behind global peers, including China and the United States, which are outpacing Europe in attracting pharmaceutical investment, initiating more clinical trials and originating a greater share of novel pharmaceutical innovations."

The report focuses on four performance areas that most directly drive life sciences competitiveness: research and innovation; the regulatory environment; the commercial environment and industrial output. It notes that the European Union (EU) retains deep scientific excellence, advanced digital capabilities, a strong industrial base and high trade performance, but that across the innovation pathway and uptake, it is ceding ground to the US and, increasingly, China – most visibly in the origin of new medicines, share of clinical trials, use of expedited regulatory pathways, as well as speed and breadth of medicines launches. Similarly, while Europe's science and industrial base is an asset, innovation conversion, as well as access breadth and speed, now define its competitiveness gaps. On these metrics, the gap relative to the US persists, and the challenge from China is evident.

However, the report identifies improvement areas that could deliver high returns in industry R&D investment, clinical trials starts, and an increased number of new active substances originating from Europe.

 **[Access the full report here](#)**

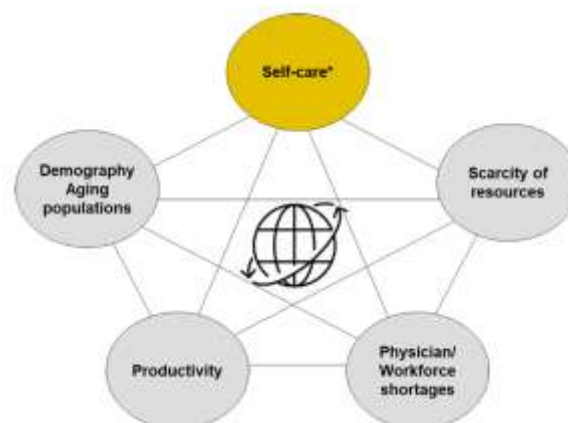
Global Self-Care Federation

The Global Social and Economic Value of Self-Care 2.0

The Global Social and Economic Value of Self-Care 2.0 is the second edition of a 2021 global study

that was designed to equip policymakers, health leaders and decision makers with robust evidence on the value of self-care.

Since publication of the 2021 study, both the global healthcare environment and the availability of data have evolved. The second edition – both an update and an addendum to the 2021 study – aims to further strengthen the evidence base for self-care as a key component of sustainable, accessible and efficient healthcare systems world-wide.



This second edition further underscores that responsible self-care is not a marginal complement for health systems but a measurable economic and social force that generates health, social and economic value at every income level. This report also provides evidence of the considerable untapped potential of self-care.

 **[Access the full report here](#)**

WHO

World Health Organization

Advancing access to quality-assured, child-friendly cancer medicines

WHO has issued its first invitation to manufacturers of childhood cancer medicines to submit an expression of interest for product evaluation by the WHO Prequalification Programme.

Each year, an estimated 400,000 children and adolescents develop cancer. Close to 90% live in low- and middle-income countries, where survival remains below 30%, compared with more than 80% in many high-income countries. Limited access to quality-assured medicines and a lack of formulations suitable for children contribute substantially to this survival gap.

The invitation to submit an expression of interest (EOI) includes twelve essential childhood cancer medicines: six prioritized medicines for

which child-friendly formulations are needed and six selected given documented access and supply gaps.

 [Further information](#)

Evidence review 2010–2025: vaccines, thiomersal & autism spectrum disorder

This review provides a current assessment of peer-reviewed studies published between 2010 and August 2025 investigating potential associations between vaccines and autism spectrum disorder (ASD), with a particular focus on the organo-mercury vaccine component thiomersal and also considers studies reporting other neurodevelopmental disorders (NDDs). It updates previous WHO reviews by assessing the methodological quality, strength of evidence and risk of bias of the

available literature. The review finds that the most methodologically rigorous primary studies do not support a causal association between vaccines, including thiomersal-containing vaccines, and ASD. Studies reporting positive associations had very low strength of evidence and high risk of bias, while none of the included meta-analyses supported a causal relationship. Overall, the evidence continues to support the safety of current vaccines with respect to ASD and other NDDs.

The review aim of the review is to provide clinicians, policymakers and public health professionals with reliable and balanced evidence to inform decision-making, strengthen vaccine confidence and contextualize ongoing scientific and public dialogue.

 [Further information](#)

CIOMS Secretariat news

CIOMS Student Award 2026

Deadline for applications: 15 December 2026

The CIOMS Student Award recognizes outstanding scientific research by medical students and carries an award of US\$ 1500. Eligible research covers medicines safety, efficacy/effectiveness, research ethics and pharmacovigilance. For this award, medicines include biological medicines, vaccines and new and advanced therapies.



For the 2025 award, CIOMS selected two winners — Bibek Shrestha, from Nepal (left) and Miguel Ángel Pardiño Vega from Mexico (right) — each receiving an award of US\$ 1500.

Dr Lembit Rägo, Director-General of CIOMS comments that, “Early involvement of medical

students in scientific research improves their understanding of evidence-based medicine. Perhaps most importantly, it demonstrates to them the value of creating new knowledge that can improve patient care.” He also notes that early engagement in research “also appears to be a predictive marker for a future successful career in medicine.”

An application for the award must include:

- a short cover letter including the student’s name, institution, country and email
- a brief description of why the application merits this award
- the published article
- one or two letters of recommendation from the student’s institution.

CIOMS encourages submissions from all countries. Previous winners include students from Australia, Indonesia, Mexico, Nepal, the Netherlands, Mexico, Uganda and the UK.

 [Further details – including for eligibility – can be found here.](#)

CIOMS cited

Scientific & other journals

- Ani CC, Chime OH, Amaefule ER, Eze A. **Data protection in pharmaceutical research in Nigeria: a socio-legal appraisal of relevant legal frameworks.** African Journal of Criminal Law and Jurisprudence. 2026; 11. <https://journals.ezenwaohaetorc.org/index.php/AFJCLJ/article/view/4418>
- Broström L, Nilsson A. **Including research subjects without decision-making capacity only as last resort.** Ethics Hum Res. 2026;48(4). <https://doi.org/10.1002/eahr.70013>
- Johnson T, Loganathan S, Jamrozik E, Parker MJ, Chan XHS. **WHO target product profiles for dengue therapeutics: an interdisciplinary analysis of ethical, regulatory, and implementation considerations.** The Lancet Microbe. Online first 101466, 2 September 2026. <https://doi.org/10.1016/j.lanmic.2026.101466>
- Lev N, Borovoi L, Elefant E, Domany E, Daniel O, Ifergane G. **A victim of its own progress: why the success of modern therapeutics forces a re-evaluation of placebo-controlled trials in migraine prevention.** Front. Neurol. 2026;17:1871028. <https://doi.org/10.3389/fneur.2026.1871028>
- Luna F. **Beyond fixed categories: dynamic vulnerability and context-sensitive inclusion in the revised Declaration of Helsinki.** JME Practical Bioethics. 2026;2:e000297. <https://doi.org/10.1136/jmepb-2026-000297>
- Marques Rodrigues JA, D'Empaire G, Mendoza Mujica I. **Bioethics, sex-gender equity, and the underrepresentation of women in cardiovascular clinical research.** EMJ Cardiol. 2026, 13 August. <https://doi.org/10.33590/emjcardiol/5W1NEY9>
- Ngerntong C. **A system-based framework for enhancing human research ethics governance in higher education: evidence from Phetchaburi Rajabhat University, Thailand.** Interdisciplinary Research Review. 2026;21(3). <https://doi.org/10.1007/s10805-025-09653-9>
- Norén GN, Durand J, Kara V, MacEntee Pileggi E, Carroll H, Sanna Hill, et al. **Artificial intelligence in pharmacovigilance: guiding principles from the CIOMS Working Group XIV.** Drug Saf. 2026. <https://doi.org/10.1007/s40264-026-01708-z>
- Ooi KH, Ooi PB, Phan CW. **An umbrella review of ethical challenges in clinical trials conducted in low and middle income countries.** Discov Glob Soc. 2026; 4, 220. <https://doi.org/10.1007/s44282-026-00580-7>
- Pinsart MG, Pirard V, Caeymaex F, Solhdju K, Cunningham-Burley S, Raven-Adams MC. **From the biomedical model to the climate-sensitive model: A necessary adjustment for research ethics committees.** Dialogues in Health. 2026; 9, 100335. <https://doi.org/10.1016/j.dialog.2026.100335>
- Ramírez-Guerrero G, Pedreros-Rosales C, Galindo P, Ulloa R, Alarcón J, Ávila S, et al. **Volume removal intolerance during net ultrafiltration in patients with acute kidney injury in the intensive care unit: protocol for a prospective multicentre observational study (VINKO).** BMJ Open. 2026; 16:e125067. <https://doi.org/10.1136/bmjopen-2026-125067>
- Reckelbus M, Van Steijvoort E, Huys I, Borry P. **Vulnerability, protection and fairness: ethical and regulatory limits in small-N gene therapy trials.** Trials. 2026; 27:488. <https://doi.org/10.1186/s13063-026-09896-w>
- Różyńska, JK. **Using AI to calculate research payments.** The American Journal of Bioethics. 2026; 26(8). <https://doi.org/10.1080/15265161.2026.2690964>
- Santos-Rocha R, Nogueira-Silva C, Jorge R, Zangão MO, Santos PC, Pimenta N, et al. **Using project management principles to plan the research and development project "Active Pregnancy".** Discov Public Health. 2026; 23, 1431. <https://doi.org/10.1186/s12982-026-02886-y>

Report

- World Health Organization. **Artificial intelligence-related Health Research: Ethics Review and Oversight.** Geneva: World Health Organization; 2026. <https://www.who.int/publications/i/item/9789240124073>

Top ten CIOMS publication downloads

1 July – 30 September 2026

2025	Artificial Intelligence in Pharmacovigilance	599
2016	International ethical guidelines for health-related research involving humans ^a	597
2025	Glossary of ICH terms and definitions (Version 9)	463
2025	CIOMS Cumulative glossary, with a focus on pharmacovigilance	362
2025	Benefit–risk balance for medicinal products	176
2005	Management of safety information from clinical trials ^b	151
2026	Introduction to MedDRA Labeling Grouping (MLG) (in Japanese) (original in English, 2024)	123
2010	Practical Aspects of Signal Detection in Pharmacovigilance	114
1999	Guidelines for Preparing Core Clinical-Safety Information on Drugs	104
2024	CIOMS Cumulative glossary, with a focus on pharmacovigilance (Anniversary Edition)	92

^a The number of 597 refers to the total number of downloads of the English, Portuguese & Spanish versions of 2016, 2016 and 2018 respectively. The guidelines are also available in: Arabic, Chinese, French, Japanese, Korean, Polish, Russian, and Ukrainian.

^b Also available in Chinese.

 [Discover all CIOMS publications](#)

Find us on the web

<https://cioms.ch>

1 July – 30 September 2026



52,692
visitors from



190
countries



42,541
subscribers

Council for International Organizations of Medical Sciences (CIOMS)

Associate partner of UNESCO | In official relations with WHO

Chemin du Pommier 42, 1218, Le Grand-Saconnex (Geneva), Switzerland
Postal address: Case postale 2100, CH-1211 Geneva 2



CIOMS Secretariat:

Secretary-General: **Dr Lembit Rägo**

Deputy Secretary-General: **Dr Samvel Azatyan**

Head Administration & Finance: **Ms Sue Le Roux**

Senior Project Manager: **Ms Sanna Hill**

Contact: info@cioms.ch