# What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

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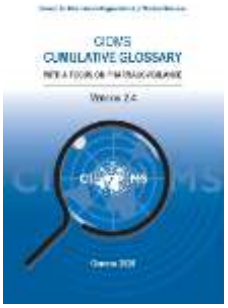
# Just published

## CIOMS Cumulative Glossary, with a focus on pharmacovigilance

**Version 2.4 — https://doi.org/10.56759/ocef1297**




Versions 2.4 of this highly popular glossary is now available for download on the CIOMS website. It compiles all the definitions from across the CIOMS Working Group reports on pharmacovigilance and related topics, including the terms and definitions in the most recent CIOMS Working Group report: *Artificial Intelligence in Pharmacovigilance*.

In standardizing terminology across global drug safety work, the glossary assists regulators, pharmaceutical companies, researchers, and healthcare systems in communicating precisely about safety issues


A Korean edition of Version 2.3 of the Glossary has also just been published. It will help Korean regulators, researchers, and pharmaceutical professionals to apply internationally- standardized pharmacovigilance terminology accurately while working in their own language.

☞ **CIOMS Cumulative Glossary: with a focus on pharmacovigilance, Version 2.4**

☞ **In Korean: CIOMS Cumulative Glossary: with a focus on pharmacovigilance, Version 2.3**

## In Japanese and Chinese: International Guidelines on Good Governance Practice for Research Institutions


The scale, complexity, and risks of biomedical research have increased dramatically. Strong governance frameworks help ensure that research institutions operate ethically, transparently and responsibly.

First published in 2023, the International Guidelines on Good Governance Practice for Research Institutions aim to assist research institutions in fulfilling their responsibilities to human research participants and their communities. Incorporating a review of existing international standards and best practices for health-related research, they also provide detailed and specific guidance on how to implement them.

CIOMS is pleased to announce that following successful collaboration with a team led by Professor Hisashi Urushihara at Keiko University, Japan, the guidelines are now available in Japanese. They have also been made available in Chinese, by the Shanghai Clinical Research Center.

☞ **International Guidelines on Good Governance Practice for Research Institutions: in English; in Japanese; in Chinese**

# In Chinese: Benefit–Risk Balance for Medicinal Products

This report, from CIOMS Working Group XII, first published in English in 2025, is now available in Chinese. Since China has become one of the largest pharmaceutical markets and research environments, making the report available in Chinese means that the guidance it contains is now accessible to many more researchers, regulators and pharmaceutical professionals, thereby strengthening shared global approaches to evaluating medicines. The translation was made by the Hainan Lecheng Institute of Real World Study. The official launch of the report was held via webinar on 5 March 2026. (See page 6.)

☞ **In Chinese: Benefit–Risk balance for medicinal products**

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# A Framework for Assessing the Trustworthiness of Scientific Research Findings

**Brian A Nosek, David B Allison, Kathleen Hall Jamieson, Susan M. Wolf**
**PNAS, 3 February 2026 — https://doi.org/10.1073/pnas.2536736123**

The trustworthiness of scientific findings (i.e. evidence and claims produced in the research process) is generating considerable debate. This new paper seeks to help answer the question, "What makes research findings trustworthy?" by providing a framework — The Trustworthiness Framework for Assessing Research Findings — that can be applied across methods, approaches, and disciplines and to foster innovation in the development of trustworthiness indicators.

The framework incorporates seven components that contribute to the trustworthy-iness of research findings, namely whether the research:

- is accountable
- is evaluable
- has been evaluated
- is well formulated
- controls bias
- reduces error

and whether the claims are warranted by the evidence. The seven components are relevant at three levels that contribute to trustworthiness:

- the research itself
- researchers conducting and evaluating the research
- organizations — including institutions, funders, and journals — facilitating and supporting the research.

To ensure broad applicability across scientific domains, the framework:

- has a systems-level perspective
- focuses on behaviours and actions that are direct indicators of trustworthiness and not proxy indicators, such as reputation
- prioritizes indicators that can, in principle, be measured to assess research trustworthiness
- is inclusive, prioritizing components and indicators that have broad applicability across a range of scientific research activities
- designed to stimulate further research and improvements in the components, levels of analysis and indicators assessing trustworthiness.

The authors conclude: "By adhering to practices that promote the trustworthiness of research findings, researchers contribute to a cumulative body of knowledge that can be relied upon by other researchers, policymakers, practitioners, and the public. In a world of misinformation, ideological campaigns, and motivated reasoning, producing trustworthy research findings may not be sufficient on its own to earn trust, but it is a necessary feature of an enterprise that is relentlessly truth-seeking."

☞ **Lead author Brian A. Nosek is Co-founder and Executive Director of the Center for Open Science.**

# CIOMS Working Group news

## Working Group updates

*Above: Members of **CIOMS Working Group XVI: Development Safety Update Report**, at their meeting in Barcelona, Spain in February 2026.*

**Working Group XVI: Development Safety Update Report** held an in-person meeting in Barcelona, Spain in February 2026. It considered how "signals" should be addressed in the Working Group's report. Subgroup 2 described how its work has focused on how to reflect reference safety information expectations in DSUR reporting without creating conflict with evolving and highly detailed European Clinical Trials Regulation Q&A materials. Subgroup 3 reported that it had agreed that development-stage DSURs should avoid implying definitive "benefit" and instead introduce the concept of anticipated benefit as a more appropriate framing during clinical development. The fourth subgroup topic (combination products and auxiliary medication) will be addressed after the first three subgroups have established their core approach. Working Group XVI's next meeting will be held virtually on 23 April 2026, followed by an in-person meeting in Geneva in September 2026.

The public consultation for the draft report of **Working Group XV: Pharmacoepidemiology for Public Health** closed on 13 March 2026. Over 600 comments were received, and the Working Group's editorial committee is now reviewing these.

## Working Group updates

**Working Group XIV: Artificial Intelligence in Pharmacovigilance** held a webinar on 6 March 2026 to introduce and explain the main concepts of its report. Over 900 attendees, representing 86 countries joined the webinar. 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. . A second webinar was held on 26 March 2026.

*Right: Presenters from **Working Group XIV: Artificial Intelligence in Pharmacovigilance** during the 6 March 2026 webinar*

# CIOMS@ international events

## 1st ISoP European Artificial Intelligence Seminar 2026: AI-Powered Pharmacovigilance: Humans in the Loop

**16 & 17 February 2026. Basel, Switzerland**

This event explored how artificial intelligence (AI) can responsibly and effectively transform pharmacovigilance (PV). Focusing on the interplay between emerging AI technologies and human expertise, it highlighted the opportunities, challenges, and ethical imperatives of AI integration in drug safety and risk management.

Three principal members of the Working Group that developed the CIOMS' *Artificial Intelligence in Pharmacovigilance* report — Julie Durand (European Medicines Agency), Vijay Kara (GSK, UK) and Denny Lorenz (Lorenz Bratti GmbH, (Germany) — led a session sharing key insights and practical perspectives from the report.


## Breakthrough 2026

**10 & 11 February 2026. Madrid, Spain**


Breakthrough 2026 brought together life sciences leaders, pharmaceutical innovators and regulatory authorities to explore how pharmacovigilance and regulatory teams are making artificial intelligence (AI) a core part of daily operations. Thus, the emphasis was on practical implementation, not just theoretical potential.

The conference included a panel session with three of the contributors to *Artificial Intelligence in Pharmacovigilance* (Report of the CIOMS Working Group XIV). Moderated by Denny Lorenz (Lorenz Bratti GmbH, Germany), the session featured Hans-Jörg Römming (Merck KGaA, Germany) and Beth MacEntee Pileggi (Johnson & Johnson, USA). Together they gave an overview of what this latest CIOMS report recommends and what it means in practice, including how to apply its guidance to life-cycle governance, transparency, data quality and human oversight as organizations move from piloting AI to applying it at operational scale.

# Hainan Lecheng Institute of Real World Study & CIOMS launch Chinese version of Benefit–Risk Balance for Medicinal Products

**5 March 2026**

The Hainan Leching Institute of Real World Study supports a national research base under China's drug regulator and helps collect and analyse real-world clinical data for evaluating innovative medical products. Together with CIOMS it organized a virtual seminar on 5 March 2026 — hosted by the institute's Deputy Secretary-General, Dr Weihong Yuan, and Dr Lembit Rägo, Secretary-General of CIOMS — to introduce the Chinese version of CIOMS Working Group XII: *Benefit–Risk Balance for Medicinal Products*. Speakers included a panel of members of the Working Group, as well as representatives of the Institute's Chinese Proofreading and Translation Expert Review Panel.

☞ **In Chinese: CIOMS Working Group Report XII: Benefit–Risk Balance for Medicinal Products**

# Save the date

***DIA Annual China Meeting, Shanghai China: 13–16 May 2026***

The meeting programme features a pre-meeting biotech day, an opening keynote "Patient voice vs drug innovation vs accessibility", an ICH day and a day focused on life-cycle drug development.

☞ **Programme information and registration**

***DIA Global Annual Meeting, Philadelphia, Pennsylvania, USA: 14–18 June 2026***

The meeting will bring together life sciences professionals to explore cutting-edge science, regulatory strategy, operational challenges and emerging therapies. A session to be given by members of **CIOMS Working Group XIV: Artificial Intelligence in Pharmacovigilance** will cover: foundational principles for ethical deployment of artificial intelligence (AI) in pharmacovigilance, including human oversight, explainability, and governance; practical use cases where AI has been successfully integrated into pharmacovigilance workflows, highlighting lessons learned and measurable impact; and regulatory expectations, validation frameworks and the role of real-world evidence in supporting AI-enabled safety decisions. The session will equip attendees with a balanced view of AI's potential and limitations in pharmacovigilance.

☞ **Programme information and registration**

***ISoP Mid-year Symposium: Collaboration in Pharmacovigilance in an Evolving Information Environment, Hatfield, UK: 9–10 June 2026***

Hosted by the University of Herefordshire, this symposium is aimed at healthcare professionals working in a regulatory, industry or university setting, or in clinical or epidemiological settings and with an interest in pharmacovigilance. The programme will enable participants to explore collaboration as both a strategic necessity and a practical enabler of modern pharmacovigilance. **Dr Stella Blackburn, President of CIOMS,** will present a session on, "Global collaboration of safety standards-evolving guidelines, joint efforts to streamline post approval safety reporting and risk management plans."

☞ **Programme information and registration**

# Regulatory news roundup

## ACT EU Accelerating Clinical Trials in the EU

### Consolidated advice pilots

The ACT EU advice pilots continue in 2026. They aim to enhance coordination within the European medicines regulatory network (EMRN) so that applicants receive harmonized advice on how to improve the quality of their applications for marketing and/or clinical trial authorisation(s), thereby facilitating the development of safe and effective medicines.

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.

The pilots are accepting new applications in 2026. Previous applicants can also reapply.

☞ **Further information**

## EC/EU European Commission/European Union

### Reform of EU pharmaceutical legislation

On 11 December 2025, co-legislators reached a provisional agreement on revamping the EU's pharmaceutical policy framework, to boost competitiveness, innovation and security of supply.

#### Supporting innovation

Agreement was reached on a regulatory data protection period (during which other companies cannot access product data) of eight years, with one additional year of market protection (during which generic or biosimilar products cannot be sold), following a marketing authorisation. Pharmaceutical companies would be eligible for additional periods of market protection if:

- the particular product addresses an unmet medical need (12 months)
- the particular product contains a new active substance, fulfilling a combination of conditions relating to comparative clinical trials, clinical trials carried out in several member states, and the obligation to apply for market authorisation within 90 days after the submission of the application for the first marketing authorisation outside the Union (12 months)
- the company obtains an authorisation for one or more new therapeutic indications that bring a significant clinical benefit in comparison with existing therapies (12 months).

A cap of eleven years on the combined regulatory protection period is envisaged.

To support earlier market entry of generic and biosimilar medicinal products, the agreement clarifies the scope of the "Bolar" exemption (which allows manufacturers to conduct certain activities during the market protection period of the original product).

#### Fighting antimicrobial resistance

A "transferable data exclusivity voucher" for priority antimicrobials is planned, giving the right to 12 additional months of data protection for one authorised product. The 12-month extension may be used once, for the priority antimicrobial or for another centrally authorised medicinal product of the same or different marketing authorisation holder.

New measures to promote the prudent use of antimicrobials include stricter requirements, such as compulsory medical prescriptions for all antimicrobials, specific information requirements to be provided with the package leaflet, and an "awareness card" in paper format in case the leaflet is made available only electronically.

Companies applying for marketing authorisation for antimicrobials, companies would also need to provide an "antimicrobial steward-ship plan" and include an evaluation of the risk for antimicrobial resistance as part of the compulsory environmental risk assessment.

#### Competitive regulatory framework

The updated rules aim at simplifying the European Medicines Agency's (EMA) internal functioning, so that it can treat market authorisation requests more rapidly. Marketing authorisation applications would be submitted electronically in a common format. Marketing authorisation for a medicinal product would be valid by default for an unlimited

period, avoiding the unnecessary administrative burden linked to renewals. (The EMA would still be able to limit validity, on safety grounds.)

### Availability of medicines

Companies holding marketing authorisations for medicinal products would be required to put in place and update shortage prevention plans for medicinal products subject to prescription. Medicinal products identified by the Commission as requiring a shortage prevention plan would be monitored at both national and EU levels, and the EMA would establish and update a list of critical shortages in the EU.

### Entry into force

The legislation's acts are expected to enter into force in 2026 following formal adoption. A transition period (18–36 months) will follow, during which Member States will update their national laws and stakeholders prepare for the new requirements. Thus, the new rules could become fully applicable in practice between 2027 and 2029, depending on how long the transition period is set and when publication of the legislation takes place.

☞ **More details on various other aspects of the provisional agreement are available in this background document**

## Commission proposal for a European Biotech Act

The EC published its proposal for a European Biotech Act on 16 December 2025. It contains a broad range of measures to strengthen the EU's biotech health ecosystem — including improvements to the clinical trials framework — to support innovation and the development of new treatments.

The Biotech Act will strengthen the existing clinical trials regulatory environment by, for example, amending the Clinical Trials Regulation to provide for a faster and simplified approval process. So initial authorisation timelines will decrease from ~106 to 75 days, and even to 47 days if no requests for additional information are made. For advanced therapy medicinal products, the option for a 50-day extension for assessment will cease to be available. The timelines for the assessment of substantial modifications to an application will also be shortened: from 96 to 47 days. These accelerations will be made possible through an enhanced role for the reporting Member State, including an integrated and coordinated ethical review and by performing the validation and assessment of a clinical trial application in parallel.

Other noteworthy changes include: the introduction of a more risk-proportionate approach to the authorisation of clinical trials; the novel concept of an EU-level investigational medicinal product core dossier; support for the uptake of artificial intelligence, clarified and harmonised application of the EU's General Data Protection Regulations rules for the processing of data; and better alignment with the revised Declaration of Helsinki.

☞ **Further information**

## Simpler and more efficient regulation of medical devices and in vitro diagnostics

The EU is a world leader in medical devices. The sector employs close to one million people, mostly in small and medium-sized enterprises. According to Medtech Europe, the European medical device market has been growing an average 5.4% per year, and based upon manufacturer prices, is estimated to make up 26.4% of the world market, and to be the second-largest medical device market after the US (46.4%). Yet current EU rules are creating unnecessary costs, bottlenecks, uncertainty for companies and delays for patients.

The EC is therefore proposing reforms that will simplify EU rules for medical devices, support the digitalization of procedures, and offer a coherent framework so that companies can respond to changing market conditions and patient needs.

Timelines to complete conformity assessments will be introduced in order to speed up access to medical devices and guarantee a continuous supply. A stronger role for the European Medicines Agency (EMA) will strengthen coordination at EU level while companies will be offered more scientific, technical and regulatory expertise. The EMA will also monitor shortages of medical devices, and a list of critical devices will be created.

Finally, the proposed reforms will underpin uniform and coherent rules for medical devices incorporating artificial intelligence applications. Combined, these measures should lead to estimated cost savings of €3.3 billion per year, including €2.4 billion in annual administrative savings.

☞ **Further information**

## One Health Compass

*One Health Compass* is a newly launched joint newsletter from the European Centre for Disease Prevention and Control, the European Chemicals Agency, the European Environment Agency, the European Food Safety Authority and the European Medicines Agency, working together on the One Health approach across Europe.


Published three times a year, the newsletter features updates on One Health initiatives, highlights from recent research, and opportunities for collaboration. Editions are available from 9 March 2026 onward.

☞ **Subscribe to One *Health Compass***

EMA European Medicines Agency

## Pilot on using clinical study data in medicine evaluation: extended

Through a proof-of-concept pilot, selected applicants can submit clinical study data to EMA as part of their initial and post-authorisation marketing authorisation applications.

Clinical data refer to individual patient data from clinical trials, including:

- clinical laboratory results
- imaging data
- patient medical charts.

To date, the process for submitting such data has been in an aggregated format as clinical summaries or as individual patient data in PDF listings. However, this can hinder data analysis and slow down evaluation. In contrast, clinical study data are stored in an electronic structured format, enabling regulators to more easily visualize and analyse the data if needed. EMA is therefore running a pilot to assess whether using clinical study data can help speed up and improve the medicine-evaluation process. The ultimate goal is to facilitate faster and better-informed access to innovative medicines for patients.

☞ **Pilot: use of clinical study data in evaluation**

☞ **Queries and applications to participate in the pilot can be sent to: rawdatapilot@ema.europa.eu.**

## FAST-EU

The heads of Medicines Agencies have launched a pilot initiative —FAST-EU (Facilitating and Accelerating Strategic Clinical Trials — as a practical way for sponsors to already try out, under the existing legal framework, shorter evaluation timelines for their multinational trials. Each month, sponsors will have an opportunity to express their interest in participating in the pilot.

☞ **Further information**

## DARWIN EU®: 100 real-world data studies

In 2022, EMA and the European Medicines Regulatory Network established a coordination centre — Data Analysis and Real World Interrogation Network (DARWIN EU®) — to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real-world healthcare databases across the European Union (EU). It enables EMA and national competent authorities in the European medicines regulatory network to use these data whenever needed throughout the life cycle of a medicinal product.

Darwin EU® recently reached an important milestone, with over 100 real-world data studies now initiated. DARWIN EU® studies support medicines regulation by answering critical questions on, for example, the use of medicines, on disease epidemiology, or on associations between medicines exposure and beneficial or adverse outcomes.

Currently, 40 partners across 19 EU countries provide access to data from over 188 million patients. It is anticipated that additional data partners will be able to join Darwin EU® in 2027.

☞ **DARWIN EU webpage**

## Common principles for AI in medicine development

Together with the U.S. Food and Drug Administration (FDA), EMA has jointly identified ten principles for good artificial intelligence (AI) practice in the medicines life cycle. These stipulate that development and use of AI should:

- align with ethical and human-centric values

- be risk-based
- adhere to relevant legal, ethical, technical, scientific, cybersecurity and regulatory standards, including Good Practices
- have a well-defined context of use
- integrate multidisciplinary expertise
- incorporate detailed, traceable and verifiable documentation of data source provenance, processing steps and analytical decisions in line with good practice requirements, and appropriate governance, including privacy and protection for sensitive data, should be maintained throughout the technology's life cycle
- follow best practices in model and system design and software engineering, and leverage data that is fit for use
- incorporate risk-based performance assessments
- carry out life-cycle management
- present clear, accessible and contextually relevant information to the intended audience, including users and patients, regarding the AI technology's context of use, performance, limitations, underlying data, updates and interpretability or explainability.

The principles are relevant for those developing medicines, as well as for marketing authorisation applicants and holders. They will underpin future AI guidance in the different jurisdictions and support enhanced international collaboration among regulators, organisations setting technical standards and other stake-holders. Guideline development in the European Union (EU) is already under way, building on the EMA AI reflection paper published in 2024.

☞ **Guiding principles of good AI practice in drug development**

## Use of Bayesian methods in clinical development

EMA's Methodology Working Party (MWP) was established by the Committee for Medicinal Products for Human Use to pool and use expertise in key areas such as biostatistics, modelling and simulation, clinical pharmacology and pharmacokinetics, pharmacogenomics and diagnostics, artificial intelligence and data science, and real-world evidence.

Currently, clarity regarding the regulatory position on when Bayesian methods can be accepted in the confirmatory setting, and the methodological requirements for addressing potential regulatory concerns, is lacking. MWP has therefore issued a concept paper proposing the development of a guideline on the use of Bayesian statistics in clinical development. The concept paper is available for public consultation, until 30 April 2026.

☞ **Concept paper available for public consultation: Use of Bayesian methods in clinical development**

## Review of Union list of critical medicines

The Union list of critical medicines identifies medicines that are critical for health systems across the European Union/European Economic (EU/EEA) Area and for which continuity of supply should always be guaranteed for European patients. It helps EMA, the Heads of Medicines Agencies and the European Commission to work together on proactive measures to avoid medicine shortages.

The list undergoes review annually, so that it remains relevant and aligned with the evolving needs of the EU/EEA healthcare systems. During the review conducted in 2025, 61 active substance groups and combinations were assessed; nine of these were added to the list.

Requests for review can be submitted to EMA by EU/EEA Member States and stakeholder groups (health care providers, patient organisations, learned societies and industry organisations).

An EMA information note issued in December 2025 outlines the methodology to be applied during future reviews

☞ **Methodology for the annual review of the Union list of critical medicines**

## Guideline of Good Pharmacovigilance Practices Module P.III

This new guideline provides EMA and Heads of Medicines Agencies guidelines for monitoring, assessing and minimising risks of medicinal products in pregnant/breastfeeding women and their children. It focuses on enhancing data collection — identifying embryo-fetal risks,

managing pharmacokinetics changes and conducting lactation studies to ensure safety — to inform therapeutic decisions. The module will help promote proactive management of safety information, and implementation of risk minimization measures to protect both mother and child.

The guideline came into effect on 9 February 2026.

☞ **Further information**

## HSA Health Sciences Authority, Singapore

### WHO maturity level 4 for medical devices

WHO has confirmed that HSA has reached maturity level 4, the highest level of regulatory performance for medical devices under WHO's global benchmarking framework.

Singapore is the first WHO Member State to attain this level for medical device regulation. The designation confirms that Singapore's regulatory system operates at an advanced level of performance with mechanisms for continuous improvement, and consistently monitoring the safety, quality and performance of medical devices throughout their life cycle, from market authorization and clinical evaluation to post-market surveillance.

Singapore is an important global hub for medical technology innovation, with around 200 manufacturers producing a wide range of devices, from in vitro diagnostics to software as a medical device.

☞ **Further information**

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

### Updated technical documents for three guidelines

Three ICH Expert Working Groups have issued an updated document package, a mapping document and training materials, respectively, associated with three technical guidelines:

- ICH harmonised Guideline E2B(R3): Individual Case Safety Report Specification
- ICH M4Q(R2): Common Technical Document
- ICH E6(R3): Good Clinical Practice.

☞ **Further information for updated ICH technical documents**

### Draft guideline on patient preference studies

Patient preference studies ask patients what matters most to them about drugs and other health interventions, such as effectiveness, side effects, safety outcomes, convenience and other factors. These studies help drug developers and regulatory authorities to understand and consider medical needs from the perspective of patients. But such studies are not used consistently.

The E22 draft guideline aims to further harmonise approaches to these studies for regulatory authorities and the pharmaceutical industry in different countries, and to support the routine inclusion of patient preferences in decision-making. In follow-up to the November 2025 endorsement and publication of the ICH E22 draft Guideline on General Considerations for Patient Preference Studies (now at the public consultation phase), the E22 Expert Working Group has issued an informational presentation and training materials.

☞ **Public consultation: ICH E22 draft Guideline on General Considerations for Patient Preference Studies, and informational presentation and training materials**

### M15 General principles for model-informed drug development

The final version of this guideline was adopted in January 2026 and has now entered the implementation phase. Before this guideline was developed, the lack of common standards meant that the integration of model-informed drug development (MIDD) hindered the integration of computational modeling and simulation methods into drug development processes. This lack of harmonisation resulted in inconsistencies in model assessment expectations, understanding of terminology, and the quality of data used in regulatory submissions. This resulted in differences in the quality of MIDD applications and documentation in regulatory submissions, particularly novel methods or applications not covered in existing, ICH guidelines were involved.

The new guideline covers general principles and good practices for the use of MIDD and harmonises expectations regarding documentation standards, model development, data used in the analysis, and model assessment and its applications.

☞ **M15: General principles for model-informed drug development: final version**

## NMPA National Medical Products Administration, China

### Spurring innovation, tightening oversight

China has revised regulations concerning drug administration to help promote drug innovation, strengthen management of online sales of medicines and reinforce drug safety supervision.

The revised regulations emphasize a clinical, value-oriented approach to drug development, encourage innovation and support the clinical application and use of new medicines. Requirements for managing clinical trials have been refined and accelerated review pathways for drug marketing authorization introduced. Clearer procedures are also provided for drug registration and for switching between prescription and over-the-counter medicines. To incentivize innovation, the regulations grant market exclusivity to eligible paediatric medicines and drugs for rare diseases and provide data protection for drugs containing new chemical substances.

The modified rules also tighten the management of drug manufacturing. In the area of distribution and use, oversight of online drug sales has been increased and greater responsibility assigned to third-party e-commerce platform operators. Additionally, support is extended to medical institutions for developing paediatric preparations to better meet the needs of children.

The regulations further reinforce drug safety supervision by specifying inspection measures and detailing procedures for quality sampling and testing.

The modified regulations will come into force on 15 May 2026.

☞ **NMPA announcement on revision of drug administration regulations**

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

### PreCheck Pilot Program Launched

FDA's PreCheck Program seeks to strengthen America's pharmaceutical supply chain by reducing regulatory barriers for domestic manufacturing facilities. Currently, more than half of pharmaceuticals distributed in the USA are manufactured overseas. Only 11% of active pharmaceutical ingredient (API) manufacturers are US-based. In response to Executive Order 14293, "Regulatory relief to promote domestic production of critical medicines," FDA hopes to facilitate the development of new US pharmaceutical manufacturing facilities by streamlining the review and inspection process for new construction manufacturing facilities that will supply finished dosage forms or APIs.

Phase I of the PreCheck Pilot Program will select companies who are developing new pharmaceutical manufacturing facilities based on alignment with PreCheck priorities. Selected companies will benefit from FDA communication and feedback throughout the facility development process.

☞ **FDA Manufacturing PreCheck Pilot Program**

## Other related news

## CIRS Centre for Innovation in Regulatory Science

### Four decades of evidence, insight and impact

CIRS R&D Briefing 100 reflects on the role CIRS R&D Briefings have had in monitoring the evolution of regulatory and health technology assessment practices, as well as supporting national and international advocacy and policy reforms. From benchmarking agency performance to exploring emerging trends such as artificial intelligence integration and collaborative pathways, CIRS is a useful resource for decision-makers navigating complex issues in the pharmaceutical landscape.

☞ **CIRS R&D Briefing 100**

## EFPIA European Federation of Pharmaceutical Industries and Associations

### Value of commercial clinical trials across Europe

Frontier Economics — commissioned by EFPIA to explore the value of commercial clinical trials across Europe — has estimated that industry-sponsored clinical trials deliver economic value to the European economy amounting to € 35.7 billion gross value added annually, broken down as follows: € 21.7 billion from industry clinical trials; € 10.4 billion and € 3.6 billion from R&D spillover benefits.

In the three years to January 2025, 8,521 clinical trials were authorised, of which 3,236 were

multi-national industry trials and 1,291 were mono-national industry trials. Yet Europe's global position has weakened: between 2013 and 2023, Europe's share of industry clinical trials worldwide fell from 22% to 12%.

Frontier Economics also analysed the potential economic benefits of increasing the number of industry clinical trials. It recommended that Europe strengthen its position in global life sciences innovation by:

- accelerating timelines for clinical trial start-up and assessment
- investing in future innovation through sustained funding for clinical research infrastructure
- providing a single, streamlined process for multi-country trials
- making the Clinical Trials Information System simple, reliable, flexible and user-friendly.

☞ **Frontier Economics report for EFPIA**

## EVAH Evidence for AI in Health initiative

### Strengthening capacity to evaluate AI tools

Verifying that AI tools for health are safe, effective and equitable, requires strong evidence from the settings where they will be used. But in low- and middle-income countries, local and regionally designed AI solutions often lack the financial and structural support needed to evaluate tools.

Wellcome Foundation, the Gates Foundation and the Novo Nordisk Foundation have therefore co-launched the Evidence for AI in Health (EVAH) initiative to strengthen local capacity to evaluate tools and invest in evidence that can guide which technologies will be adopted and scaled. Local validation is crucial to mitigating risks that can worsen, rather than reduce, health disparities.

EVAH will work with country partners to select tools for evaluation that align with local health priorities and can be integrated into primary and community healthcare settings. The tools will span a wide range of AI technologies, such as:

- prediction models
- computer vision
- large language models
- multimodal AI

Technologies that are designed for resource-limited settings and trained on data that accurately reflects the populations they are intended to operate in will be prioritized.

The first requests for proposals will support locally led evaluations of AI-enabled decision support tools. The tools should be ready for use and designed to assist frontline health workers in sub-Saharan Africa and south and south-east Asia with clinical tasks.

EVAH is run in partnership with the Abdul Latif Jameel Poverty Action Lab and the African Population Health Research Centre; both organizations are experienced in carrying out high-quality research and analysis that informs policy in low- and middle-income countries.

☞ **Further information, including for requests for proposals can be found here**

## WCO World Customs Organization

### Facilitating vaccination programmes and enhancing preparedness

Vaccine production is currently concentrated in a few countries, making trade a vital means for deploying vaccines globally. But the current classification of vaccines for human use in the Harmonized System (HS) — the international classification of goods that gives every traded product a standardized code — provides insufficient granularity for assessing international trade flows and straightforward implementation of trade policies for these vaccines. Moreover, vaccines are classified under just two subheadings: *human medicine* and *veterinary medicine*.

HS 2028 has introduced new headings and subheadings for vaccines representing significant current or expected trade volumes and addresses priority diseases where immunization is vital. The new structure distinguishes outbreak-prone diseases from endemic ones and aligns with WHO vaccination guidance by covering vaccines recommended for all programmes, for high-risk groups, for programmes with specific characteristics, and for diseases of local or sporadic nature.

These additions in the HS will provide visibility to products critical to health programmes and emergency response, enabling faster customs clearance and ease of identification. The changes, which will come into effect on 1 January 2028, to allow time for national adaption.

☞ **Further information**

WMA World Medical Association

### Expert meetings on revision of Declaration of Taipei

WMA adopted the most recent version of the Declaration of Taipei during its 67th General Assembly in October 2016 in Taipei, Taiwan. It serves as a foundational document that provides ethical guidelines for the collection, storage and use of health data and biological materials in research, particularly in relation to biobanks and health databases. It complements the Declaration of Helsinki, which focuses on broader ethical principles for medical research involving human subjects.

However, since the most recent revision of the Declaration of Taipei, developments in big data, digital health records, artificial intelligence, and new models of research using large datasets, have radically changed how health data is used and shared. Additionally, the Declaration of Helsinki was revised in 2024, and the two documents need to be aligned so that both reflect consistent principles regarding consent, privacy, transparency and trust in data-driven research.

WMA has therefore initiated a revision process with open expert meetings. Open expert meetings were held in Taipei, Taiwan in December 2025 and in São Paulo, Brazil in March 2026. A third meeting will be held in the Vatican, Italy 30 May – 2nd June 2026.

☞ **If you are interested in following the revision process, you can sign up to receive updates**

# CIOMS Secretariat news

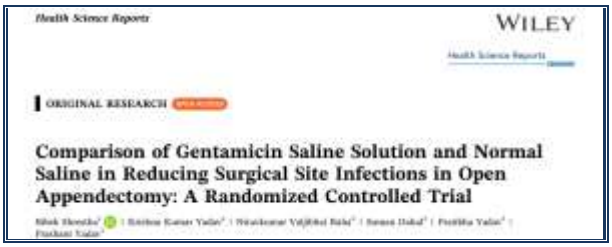
## Winners of 2025 CIOMS Student Award

The CIOMS Student Award recognizes medical students for outstanding contributions to medicine through excellence in scientific research and scholarly publication.

For the 2025 award, CIOMS received a large number of high-quality submissions. These were evaluated by Dr Stella Blackburn (CIOMS President), Dr Lembit Rägo (CIOMS Secretary-General), Dr Samvel Azatyan (CIOMS Senior Adviser) and Dr Shanthi Pal (Pharmacovigilance Team Lead at World Health Organization Headquarters). Dr Blackburn commented: "We were delighted to receive such a high number of quality papers submitted for consideration of the medical student award. Choosing winners was extremely difficult, but we felt that the papers by **Bibek Shrestha** ("Comparison of gentamicin saline solution and normal saline in reducing surgical site Infections in open appendectomy: a randomized controlled trial") and **Miguel Ángel Pardiño Vega** ("SGLT-2 inhibitors after acute coronary syndrome: a preventive approach for heart failure-related complications: a meta-analysis") were especially good. We would also like to thank the other students who submitted their papers for consideration."

Bibek Shrestha (right), 25, is in his final year of medical studies at Maharajgunj Medical Campus, Tribhuvan University Teaching Hospital, in Kathmandu, Nepal. He has a strong interest in internal medicine and clinical research, particularly in the fields of respiratory and neurological disorders. He hopes to pursue residency training in internal medicine and build a career as a physician-researcher, contributing to evidence-based care and improving health-care outcomes in resource-limited settings.

Bibek is actively involved in medical student organizations, academic conferences and research projects. He also enjoys mentoring junior students and engaging in international academic collaborations.


Health Science Reports WILEY

ORIGINAL RESEARCH

**Comparison of Gentamicin Saline Solution and Normal Saline in Reducing Surgical Site Infections in Open Appendectomy: A Randomized Controlled Trial**

Miguel Ángel Pardiño Vega (below), 23, is in his fifth year of a bachelor's degree in medicine at the Escuela Superior de Medicina, Instituto Politécnico Nacional (IPN), in Mexico City. He will complete his clinical training at Médica Sur Hospital, also in Mexico City. Miguel plans to specialize in internal medicine, followed by cardiology, with a focus on cardio-vascular disease and evidence-based medicine. His goal is to pursue a career that integrates clinical practice, academic research, and international collaboration.

Miguel has participated in clinical research projects with the Instituto Nacional de Cardiología "Ignacio Chávez" and the University of California, San Diego. He is also a member of a research team composed primarily medical students from across Latin America and focused on collaborative academic and clinical research. He has contributed to peer-reviewed publications, presented at national and international congresses, and participated in mentoring and academic leadership activities among medical students.


American Journal of Therapeutics

SGLT-2 Inhibitors After Acute Coronary Syndrome: A Preventive Approach for Heart Failure-Related Complications: A Meta-Analysis

Commenting on the award, Dr Rägo noted: "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 added that early engagement in research "also appears to be a predictive marker for a future successful career in medicine."

CIOMS warmly congratulates the two award recipients and wishes them every success in their future careers.

☞ **Applications for the 2026 CIOMS Student Award can be submitted any time between now and 15 December 2026. Details regarding eligibility, application requirements and the selection process can be found here.**

## CIOMS welcomes Ibero-American Society of Pharmacogenetics and Pharmacogenomics as new member

At its meeting on 23 March 2026, the Executive Committee approved the application for CIOMS membership of the Ibero-American Society of Pharmacogenetics and Pharmacogenomics (SIFF) (Red Iberoamericana de Farmacogenética y Farmacogenómica (RIBEF)).

Founded in 2006, SIFF aims to use pharmacogenetic knowledge in healthcare to improve the safety and effectiveness of pharmacological treatments in humans. To achieve this, it promotes research, high-quality teaching and the use of evidence-based clinical guidelines. It seeks facilitate access to and safe use of medicines for all populations, especially the most vulnerable: indigenous populations, children, the elderly, and women. Its activities include collaboration with members and institutions in regional initiatives, networks and joint publications, across multiple Spanish- and Portuguese-speaking countries.

As an international member organization of CIOMS, SIFF has voting rights at the CIOMS General Assembly and will be able to nominate a representative to the CIOMS Executive Committee in 2028.

☞ **SIFF / RIBEF**

## *CIOMS cited*

### Scientific journals

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## Top ten CIOMS publication downloads 1 January – 31 March 2026

| | | |
|---|---|---|
| 2025 | Artificial intelligence in pharmacovigilance | 1921 |
| 2025 | CIOMS Cumulative Glossary, version 4 [a] | 1855 |
| 2025 | Benefit–risk balance for medicinal products (English + Chinese versions) | 653 |
| 2025 | Glossary of ICH terms and definitions (Version 9) | 598 |
| 2016 | International ethical guidelines for health-related research involving humans [b] | 249 |
| 2025 | Severe cutaneous adverse reactions (SCAR) | 150 |
| 2024 | Real-world data and real-world evidence in regulatory decision making [c] | 138 |
| 2024 | Introduction to MedDRA Labeling Grouping (MLG) | 137 |
| 2005 | Management of safety information from clinical trials [c] | 131 |
| 2024 | Practical Aspects of Signal Detection in Pharmacovigilance | 129 |

[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

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