

# CIOMS Working Group XIV Upcoming report on AI in pharmacovigilance

EMA/HMA Multi-Stakeholder Forum  
on EudraVigilance and Signal  
Detection | 5 November 2025

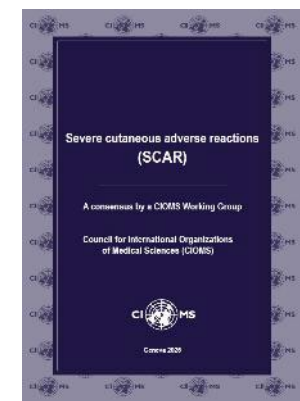
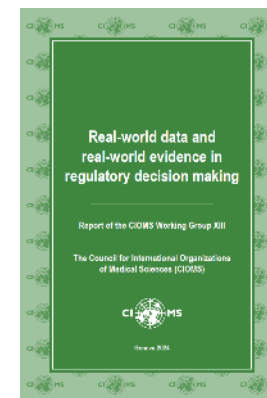
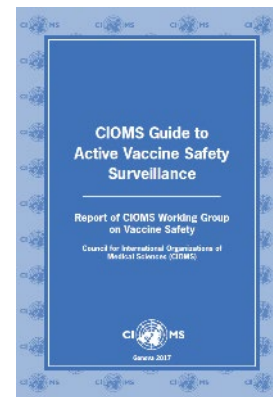
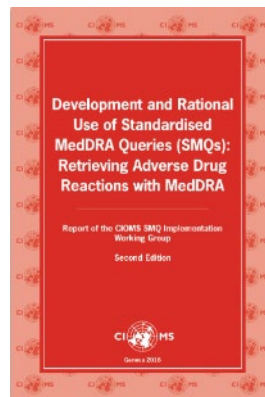
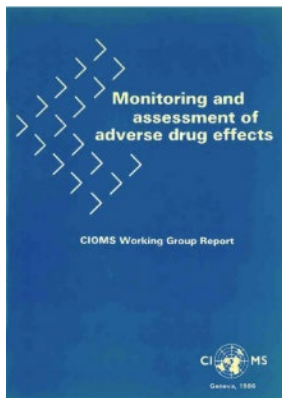
Julie Durand | Pharmacovigilance Office | EMA



# Council for International Organizations of Medical Sciences



- Non-governmental, non-profit organisation founded by WHO and UNESCO in 1949
- 41 member organisations; links with WHO, UNESCO, ICH
- Mission: advance public health through guidance on health research and policy including ethics, medical product development and safety
- Areas of work: bioethics, pharmacovigilance, product development
- 90+ available publications (including translations)



# CIOMS Working Group XIV

- Expert group formed in 2022
- Aim: address the use, opportunities, and challenges of AI specifically within the field of PV
- Senior scientists with expertise in PV and/or AI from drug regulatory authorities, biopharmaceutical companies, non-commercial research organisations, academia...

## Artificial intelligence in pharmacovigilance

Proposal to form a CIOMS Expert Working Group

February 2, 2022

### Consensus action proposed

An Expert Working Group managed by the Council for International Organizations of Medical Sciences (CIOMS) is proposed. The objective of this Working Group would be to establish and promote principles and guidance for the use of artificial intelligence or intelligence augmentation in the field of pharmacovigilance. While general guidance and regulation is being developed for the use of methods seeking to achieve artificial intelligence across other technical and scientific disciplines, the aim of the proposed CIOMS Expert Working Group would be to address its use, opportunities, and challenges specifically within the field of pharmacovigilance. As such, the CIOMS Expert Working Group would build on and complement the broader initiatives underway.

### Background

Since the early 2000s, the ability of computer algorithms to solve pre-specified tasks previously performed by human specialists has rapidly evolved. This falls within a field of research referred to as Artificial Intelligence born in the 1950's and dedicated to the study of intelligent agents – systems that can perceive their environment, act autonomously to achieve certain goals and adapt their behavior over time. Intelligence augmentation is the combination of artificial and human intelligence seeking to complement and enhance human specialist performance.

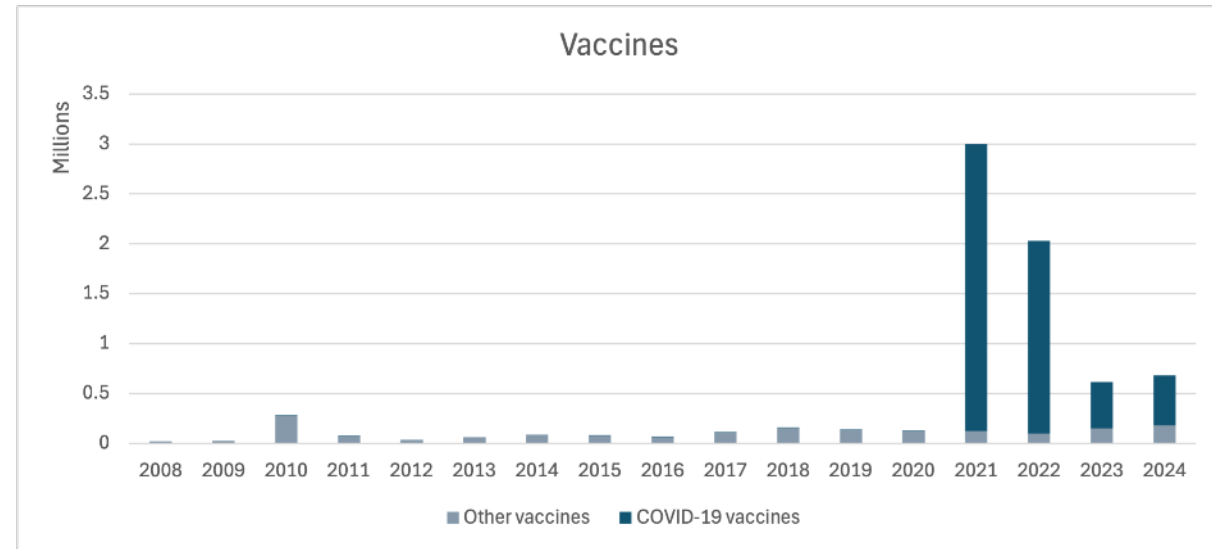
Today, artificial intelligent agents are approaching human-level performance at specific tasks such as speech and image recognition, vehicle navigation and protein structure prediction. On, for example, breast cancer prediction<sup>1</sup> and strategic board games like chess and Go, algorithms outperform human experts. In other domains, humans supported by computers provide the best possible performance. Computer algorithms have the advantage of being able to work relentlessly unaffected by external factors like emotions and cognitive biases, and processing extremely large amounts of data. At the same time, algorithms so far perform well only on tasks that are narrow in scope and have clearly defined target functions. They require access to reliable and relevant training data (or in the case of reinforcement learning, hard and fast policies for evaluation), which are usually not available for more ambiguous tasks.

<sup>1</sup> <https://www.nature.com/articles/s41586-019-1799-6>



# The case for AI in PV

- Volume and complexity of data
- AI potential to:
  - improve efficiency
  - improve consistency
  - augment data insights

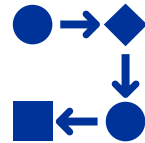


***Number of vaccine reports received annually in VigiBase (accessed April 2025)***

# Report intent, scope and target audience



Broad **framework of best practices** for developing & implementing AI in PV  
(not a detailed technical guide)

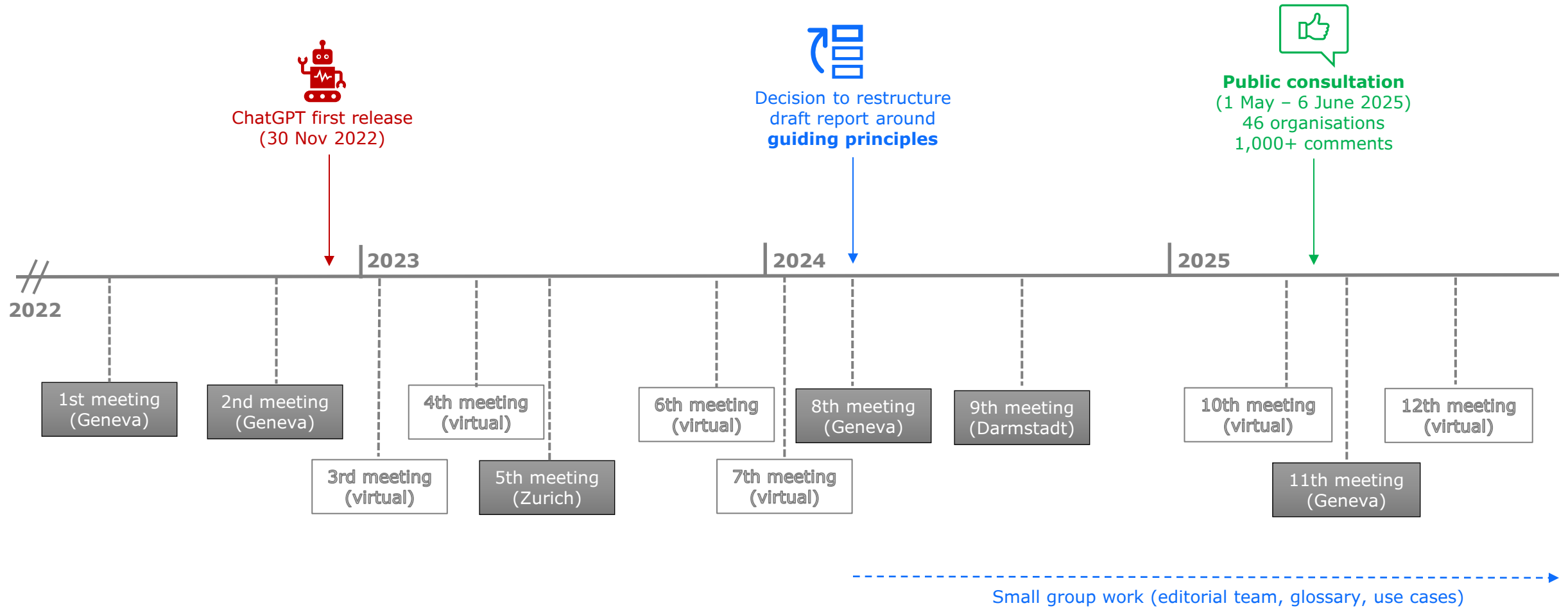


Collection, organisation, analysis, communication of **ICSRs** from any source



Professionals and organisations **working in PV** and/or **researching or developing AI** systems for the PV space

# Drafting journey



# Contents

- Executive summary
- Chapter 1 - Introduction
- Chapter 2 - Landscape analysis
- Chapter 3 - Risk-based approach
- Chapter 4 - Human oversight
- Chapter 5 - Validity & Robustness
- Chapter 6 - Transparency
- Chapter 7 - Data privacy
- Chapter 8 - Fairness & Equity
- Chapter 9 - Governance & Accountability
- Chapter 10 - Future considerations

## Guiding principles

## Appendices

1. Glossary
2. Comparison table of guiding principles
3. Use cases
  - A. LLMs data extraction for case processing
  - B. Case deduplication
  - C. AI translation assistant
  - D. LLMs for context-aware SQL
  - E. Causality assessment of adverse drug reactions
  - F. Process efficiencies supporting signal detection
  - G. Generative AI: synthesis and summary from a large unstructured safety document repository for facilitating pharmacovigilance evaluations
  - H. AI to support diagnosis and prediction of (hydroxy)chloroquine retinopathy
4. Content on Explainability and Fairness & Equity
5. CIOMS WG membership and meetings
6. Public consultation commentators

# How were the guiding principles selected?

	EU	Australia	Canada	Singapore	UK	US	PAHO	WHO	OECD
<b>Human Oversight</b>	✓	✓	✓		✓	✓	✓	✓	✓
<b>Validity &amp; Robustness</b>	✓	✓	✓		✓		✓	✓	✓
<b>Data Privacy</b>	✓	✓			✓	✓	✓		
<b>Transparency</b>	✓	✓	✓	✓	✓		✓	✓	✓
<b>Accountability</b>	✓	✓	✓	✓	✓	✓	✓	✓	✓
<b>Societal well-being</b>	✓	✓		✓			✓	✓	✓
<b>Environmental well-being</b>	✓	✓						✓	✓
<b>Fairness &amp; Equity</b>	✓	✓	✓	✓	✓	✓	✓	✓	✓
<b>Explainability</b>	✓	✓		✓	✓	✓		✓	✓
<b>Safety</b>	✓	✓	✓		✓	✓		✓	✓
<b>Governance</b>	✓				✓			✓	

*Comparison of CIOMS Working Group XIV guiding principles for artificial intelligence across regional and country government institutions, and international organizations*

# Risk-based approach

- Risks may affect **patient safety**, trust and engagement, efficiency, compliance...
- Risk assessment based on **AI system, context of use, impact** and **likelihood** of risks materialising
- Risk-based approach applies to the **other guiding principles**: human oversight, validity & robustness, transparency, fairness and equity, data privacy
- **Regular review** based on system's performance

*By focusing efforts and resources where they most matter, a sound risk-based approach enables organisations to make the most of AI capabilities while ensuring that neither patient safety nor PV stakeholders are adversely affected.*

# Human oversight

- Extent and nature of human oversight should follow **risk-based approach**
- Quality assurance principles should be applied
- **Transformation of roles** and skillsets mandates agile change management and training strategies

*Human oversight supports the optimisation of the performance of AI systems deployed in PV and increases trustworthiness and accountability.*

# Validity & Robustness

- Performance evaluation should demonstrate acceptable and robust results for **intended use** under realistic conditions
- Sufficient representation of relevant types of data in test sets to detect **biases**
- **Generalisability** across intended deployment domain
- Special attention to PV events' rarity (e.g., safety signals, duplicates)
- Monitoring for performance **degradation** and data drifts

*PV professionals and decision makers must learn to critically appraise AI systems whether they acquire them or participate in their development.*

# Transparency

- **Nature** of AI system including model architecture, expected inputs and outputs, level and type of human-system interaction
- Performance evaluation **results** should give clear and comprehensive picture of the AI model's effectiveness and limitations in the intended PV application
- **Explainability**
  - When known, general principles and logic by which AI model functions and arrives at its outcomes
  - Lack of explainability should be acknowledged and discussed

*Declaring when and how AI systems are used for core PV tasks is critical for building trust among domain experts, decision makers, regulatory authorities, and the public.*

# Data privacy

- Application of AI in PV use cases involving protected data should consider **principles for research** activities with human subjects.
- Appropriate **safeguards** are needed to address data privacy requirements.
- High computer power, data linkage, complex PV ecosystem, and use of **GenAI** may pose increased risk of compromising data privacy.
- Global and country-specific legal and **regulatory frameworks** (e.g., GDPR, HIPAA) have been established to protect data privacy.

*The applications of ethical principles most relevant for the use of AI in PV are data privacy, fairness, and equity.*

# Fairness & equity

- Screening, identifying and excising **explicit or potential bias** is key to mitigating risk, determining AI applicability and limitations, and defining acceptable performance.
- AI outputs should be relevant to **all exposed populations**
- Training and performance evaluation reference data sets should be scrutinised for adequate **representation** and performance evaluated in relevant **subgroups** when possible

*Striving for fairness and equity in the development and use of AI in PV is both a regulatory and ethical imperative.*

# Governance & accountability

- Robust governance and clear accountability are crucial for the success of AI initiatives.
- These ensure that AI systems are used safely, responsibly and ethically, and in **compliance** with all applicable legal and regulatory requirements while fostering **trust and transparency** among stakeholders.
- Clearly defined **roles and responsibilities** enable all stakeholders to understand their accountability and obligations to effectively oversee AI systems.

*As AI technology evolves, governance and accountability frameworks will need to be adapted. New risks and challenges will emerge, requiring updated principles and practices. Continuous review and adaptation are essential for staying ahead of these changes.*

# Governance framework grid

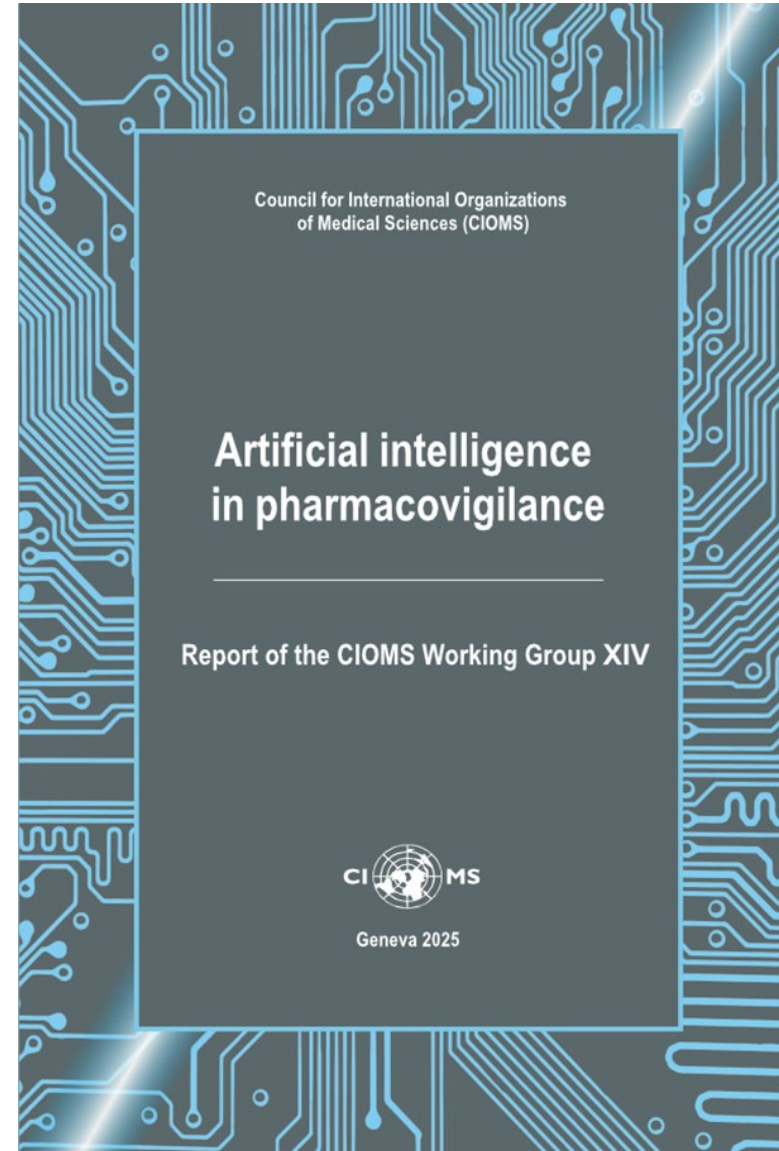
	Collection of specifications, requirements	Development & change management	Pre-deployment sign-off	Post-deployment hyper-care	Routine use
Risk-based approach					
Human oversight					
Validity & Robustness					
Transparency					
Data privacy					
Fairness & Equity					
Governance & Accountability					

*A governance framework grid can serve as a structured guide to help relevant parties document key elements throughout the lifecycle of the AI system.*



# Watch out for

- Final report to be released later this year
- Dedicated webinars
- Conference sessions
- Journal article



# Acknowledgements

- The contents of this presentation are based on the draft CIOMS report on AI in PV as well as published CIOMS materials.
- The presentation provides a very high-level overview of selected chapters and does not do justice to the depth and richness of the full report.
- The report has drawn on the contributions from a broad group of members.
- As for other CIOMS reports, the authors alone are responsible for the views expressed, and those views do not necessarily represent the decisions, policies or views of their respective institutions or companies.





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# Thank you

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