CIOMS Working Group XIV consensus report on *Artificial Intelligence in Pharmacovigilance*

6 March 2026
2 pm - 3.30 pm CET*

*Corresponds to 5 am - 6.30 am PDT, and 8 am - 9.30 am EDT

Biographical notes

Lembit Rägo
Secretary-General,
CIOMS, Switzerland

Lembit Rägo, MD, PhD, was a Professor of Clinical Pharmacology (Tartu University, Estonia) and founder and first Director General of the Estonian Drug Regulatory Authority, State Agency of Medicines. In December 1999, he joined the World Health Organization (WHO) Headquarters, Geneva, as Coordinator of Quality Assurance and Safety: Medicines (QSM) team which included activities related to International Nonproprietary Names (INNs), Quality Assurance, Pharmacovigilance, Regulatory Support and Fighting Falsified Medicines. In 2001, Dr Rägo laid the foundations for the WHO Prequalification of Medicines Programme, which he continued to develop until he left WHO. From September 2013, Dr Rägo served as the Head/Director of WHO's Regulation of Medicines and Other Health Technologies unit which first time united all regulatory activities related to medicines, vaccines, biologicals and medical devices into one single entity. Since 2000, he has served as observer to ICH, first representing WHO and now CIOMS.

He is well known to many senior regulators in all parts of the World, frequent speaker in different international fora and has numerous publications including on several aspects of regulatory affairs.

He was appointed Secretary-General of CIOMS in April 2016.

Elizabeth MacEntee Pileggi
Sr Director, Safety Information Management and Automation, Johnson & Johnson, USA

Beth is a highly accomplished pharmacovigilance executive with more than 30 years of experience in the pharmaceutical industry. A Registered Nurse by training, Beth received her Bachelor of Science in Nursing from Widener University and Master's in Business Administration from Wilmington University. Within the pharmaceutical industry, she has progressed through increasingly senior leadership roles, shaping global pharmacovigilance operations, case management, and the management of enterprise safety system platforms. Beth brings deep expertise in developing and executing strategic initiatives that drive operational excellence while ensuring compliance with worldwide regulatory requirements. She specializes in process and technology optimization, leading large-scale case management transformations through automation and digital innovation. Known for her strategic leadership, collaborative approach, and commitment to innovation, Beth has a strong track record of advancing pharmacovigilance capabilities in complex, regulated environments. Currently, Beth serves as Senior Director at Johnson & Johnson, responsible for Safety Information Management and Automation within Global Medical Safety. In this role, Beth leads the maintenance, advancement, and evolution of pharmacovigilance safety systems, driving modernization, digitization, and the application of artificial intelligence to deliver transformative solutions.

Julie Durand

Senior Pharmacovigilance Specialist, European Medicines Agency, The Netherlands

Julie is a senior pharmacovigilance specialist at the European Medicines Agency. She has dedicated the better part of her 20 years at EMA to a broad spectrum of signal management activities including signal detection, data analysis, and guidance development (e.g., GVP). Her experience has also extended to collaborative, multi-stakeholder initiatives such as IMI PROTECT, where she contributed to research aimed at improving pharmacoepidemiology and pharmacovigilance methods, with a focus on electronic healthcare records. In recent years, she has focused on exploring how AI and data science can be applied to streamline or enhance pharmacovigilance activities. This interest and expertise led to her involvement in CIOMS Working Group XIV. Beyond pharmacovigilance, she supports the implementation of the broader AI workstream of the EMA/Heads of Medicines Agencies Network Data Steering Group's workplan, overseeing guidance, policy and product support activities. Julie holds a PharmD and an MSc in drug regulation and has recently expanded her expertise with an MSc in data science.

Niklas Norén

Chief Science Officer, Uppsala Monitoring Centre, the WHO Collaborating Centre for International Drug Monitoring, Sweden

Niklas Norén is Chief Science Officer at the Uppsala Monitoring Centre, the WHO Collaborating Centre for International Drug Monitoring, and a member of its executive management team since 2009. He has published extensively on artificial intelligence in observational medical data, primarily adverse event reports and electronic medical records. His research has resulted in scientific papers on duplicate detection and subgroup discovery that have been internationally awarded. He is a member of the editorial board for Drug Safety, and he has led several international collaborative projects in pharmacovigilance including the signal detection work-package in IMI PROTECT; the work-packages on detecting substandard medicines and drug dependence in Monitoring Medicines; and the social media analytics work-package in IMI WEB-RADR. He is a member of the CIOMS XIV working group on Artificial Intelligence in Pharmacovigilance. Niklas holds a PhD in Mathematical Statistics from Stockholm University in 2007 and a MSc in Engineering Physics from Chalmers University of Technology in 2002.

Denny Lorenz

Executive Director and Principal Consultant, Lorenz Bratti GmbH, Germany

Denny Lorenz has over 20 years of experience in pharmacovigilance, with deep expertise in global operations, automation, and artificial intelligence.
He spent many years at Bayer AG, Berlin, where he led global teams and large-scale programs in adverse event case processing and safety surveillance. He was responsible for the global PV Systems before serving as Therapeutic Area Head for case processing in Specialty Medicine and Consumer Health, including three years based in Brazil. His work includes designing end-to-end PV processes, complex sourcing models, and strategic technology implementations.
He holds a background in business administration, informatics, and consumer health care.
Denny is a member of CIOMS Working Group XIV. His current focus is the responsible adoption of AI in PV, balancing innovation with regulatory compliance, quality, and trust.

Ravi Patel
Senior VP, Global Patient Safety & Clinical Development, United Therapeutics, USA

Ravi Patel is a global patient safety executive with more than two decades of experience across multinational pharmaceutical organizations, including Bayer, Alexion, and United Therapeutics Corporation. His leadership spans global oversight of patient safety for small molecules, biologics, and medical devices across multiple therapeutic areas & now Xenotransplantation and Organ manufacturing.
He is recognized for transforming and modernizing Global Patient Safety and Pharmacovigilance functions across the full product lifecycle, integrating scientific rigor, operational excellence, and regulatory compliance. Ravi's approach consistently embeds patient safety as a core enterprise value through proactive risk management and robust global systems. More recently, he has led strategic collaborations with global technology partners to responsibly advance the use of artificial intelligence within patient safety and medical sciences, with a focus on accelerating drug innovation, with emphasis on meaningful gains in speed, quality data, decision confidence, and long-term sustainability.
Ravi's work is centered on advancing global patient safety in parallel with the continued evolution of the medical sciences industry , supporting the evolution of global safety standards and best practices and he is an active contributor international pharmacovigilance forum, including multiple CIOMS working groups, ISoP, PV Legal & others.

Thomas Henn
Director, UTEL QPPV, Global Patient Safety, United Therapeutics, UK

Education: BSc, Biochemistry, PhD Cancer Research, Epidaemiology Diploma
More than 20 years industry working in drug safety with as a drug safety consultant, CROs and for a variety of large global and mid sized and small pharma and biotech companies. Worked in a variety of different PV and pharma roles including overseeing CTD and NDA compilation and submission; inspection and audit support, developing regulatory compliance PV systems. Experienced QPPV. Has been with UTC as UT QPPV for over 10 years.
Active member of CIOMS XIV Working Group for over 2 years. Active member and contributor to a number of international organizations, including DIA, PV Legal, ISoP.

Hua Carroll
Senior Director, Head of ICSR Medical Evaluation/Global Safety Officer, Biogen, USA

Dr. Carroll is a recognized PV leader in industry and has been invited to participate in industry forums to share her expert opinion. She has 20+ years' experience in the field, and holds a unique skill set that straddles pharmacovigilance (PV), safety operations and medical safety. Her expertise includes ICSR case processing and medical assessment, safety signal detection, and benefit/risk management in both clinical and post-marketing settings. Dr. Carroll obtained her M.D. degree from Beijing Medical University, and practiced as an OB/GYN. At Biogen, she leads the ICSR Medical Evaluation team, and serves as Global Safety Officer for assigned programs, accountable for those programs' safety surveillance activities and benefit/risk assessment. Dr. Carroll is passionate about artificial intelligence (AI) in PV to improve data quality, safety signal detection and evaluation, and thereby, ultimately improve patient safety.

Vijay Kara
Director, Safety, Innovation and Analytics Group, GSK, UK

Vijay Kara serves as a Director within the Safety Innovation and Analytics group, part of GSK's Global Safety organization. He is a seasoned pharmacovigilance professional with over 15 years of experience in the field.

Throughout his career, Vijay has held various roles in multiple pharmaceutical companies, acquiring expertise in signal detection and management, risk management, and preparing regulatory submissions for new products and indications, license renewals, in addition to experience in safety governance.
His contributions have led to multiple peer-reviewed publications in pharmacovigilance including in the field of AI in PV.

Benny Ling
Scientific Reviewer, Marketed Pharmaceuticals Bureau, Health Canada, Canada

Benny Ling is a scientific reviewer in the Marketed Pharmaceuticals Bureau in Health Canada, which is responsible for post marketing surveillance of pharmaceutical drugs. He has over 20 years of experience at Health Canada in the regulatory field of pharmaceutical drugs, natural health products, and chemicals. Aside from his regulatory work, Benny has been involved with systematic review methodology and innovation projects utilizing artificial intelligence within Health Canada. Benny holds a Master's degree in Pharmacology and Toxicology from the University of Western Ontario.

Walter Straus
Vice President, Clinical Safety and Risk Management, Moderna, USA

Walter Straus serves as Vice President in Clinical Safety and Risk Management at the biotechnology firm, Moderna. He is a physician and epidemiologist with more than 30 years of combined experience in research in government and industry. Dr. Straus was an Epidemic Intelligence Service (EIS) Officer then on permanent staff at the Centers for Disease Control and Prevention (CDC, Atlanta). He then worked for >20 years at Merck & Co. Inc. where he led teams supporting the development and or post-authorization assessment of numerous small molecules and vaccines. He is former Chairman of the Board of Public Responsibility in Medical and Research, has served on the Executive Board of the Harvard Multi-Regional Clinical Trials program (MRCT), and on the US HHS Secretary's Advisory Committee on Human Research Protection (SACHRP). He has contributed as member of several CIOMS activities, including the Working Group on Drug-Induced Liver Injury, CIOMS Guide to Active Vaccine Safety Surveillance, and Working Group XIV – Artificial Intelligence in Pharmacovigilance.