CIOMS Working Group XII consensus report on *Benefit-Risk Balance for Medicinal Products*

10 September 2025
8 am - 9.30 am EDT*

*Corresponds to 5 am - 6.30 am PDT, and 2 pm - 3.30 pm CEST

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.

Graham Thompson
Regulatory Intelligence Director and Decision Analyst, *AstraZeneca, USA*

Graham is currently a Regulatory Intelligence Director and Decision Analyst in Respiratory and Immunology at AstraZeneca. Prior to his current role, he spent 13 years with the U.S. Food and Drug Administration's Office of Strategic Programs. His team directly supported clinical review teams with especially challenging NDAs by applying qualitative and quantitative benefit-risk assessment methods. He also provided strategic planning, policy analysis, guidance development, program and process improvement, and decision framework development for a wide range of CDER offices, initiatives, and user fee negotiations.

Carmit Strauss
***Executive Director, Head of Risk Management, Organ Toxicity and Benefit Risk**, Takeda, USA*

Carmit Strauss PharmD, is an Executive Director at Takeda overseeing the risk management, Organ toxicity and Benefit Risk centers of excellence. She is also an Adjunct Associate professor at the University of Southern California school of pharmacy. Carmit obtained her PharmD at the University of Southern California (USC) and holds a Bachelor of Science degree in Microbiology Immunology and Molecular Genetics from University of California Los Angeles (UCLA). Carmit completed her industry post-Doctoral fellowship at Baxter Bioscience.
Carmit has extensive experience in Benefit Risk management working in various leadership roles within Safety and Pharmacovigilance and Medical Affairs. Carmit has a broad range of experience in risk management and benefit risk assessment planning, risk minimization and REMS design, implementation and evaluation. Her expertise also includes risk communication and patient-centered approaches and methodologies. In her current role, Carmit provides leadership and subject matter expertise in Risk Management, Benefit/Risk assessment and Organ Toxicity and ensures identification and mitigation processes are continuously improved to reflect regulatory trends/guidelines and best practices. Prior to Takeda, Carmit held multiple positions at Amgen, Baxter Bioscience and Protalix Biotherapeutics as a safety and medical affairs lead in various therapeutic areas.
Carmit has been actively collaborating with various cross-industry groups and projects, she is a member of CIOMS XII working group and a board member of REMS Industry Consortium. Carmit has authored multiple scientific benefit risk and risk management abstracts and publications as well as presented at many benefit risk/risk management related conferences on various topics.

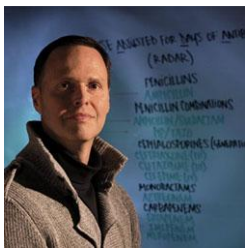
Leo Plouffe
Vice President, Gilead, USA

Leo Plouffe, MD CM, is Vice President at Gilead Sciences, Inc. He was Global Head of Patient Safety for the past three years, and has recently become Head of Medical Affairs Research. He started his career at the Medical College of Georgia, where he served as Professor and Section Chief of the Reproductive Endocrinology section. He pursued his career at Eli Lilly and Bayer Pharmaceuticals, holding positions of increasing responsibility and culminating as Vice President, Global Head of Benefit-Risk Management in Patient Safety and Pharmacovigilance.

Born in Montreal, Canada, Dr. Plouffe earned his medical degree and completed residency in Obstetrics and Gynecology at McGill University, followed by a fellowship in Reproductive Endocrinology and Genetics at the Medical College of Georgia. He is dual-boarded by the American Board of Obstetrics and Gynecology and a member of the Royal College of Physicians and Surgeons of Canada. He enjoys traveling with his wife, coupled with sampling foods from around the world and capturing the memories in pictures.

Stéphanie Tcherny-Lessenot
Head of Benefit-Risk Evaluation, Epidemiology & Benefit-Risk Evaluation, Sanofi, France

Stephanie Tcherny-Lessenot, public health physician, has over 20 years of experience working in pharma companies on Pharmacoepidemiology and Benefit-Risk evaluation to support market access, pricing, benefit-risk and safety evaluation. Stephanie is one of the leading experts in the epidemiology methods and qualitative and quantitative benefit-risk field and has conducted many benefit-risk analyses for development and marketed drugs for over 13 years. Stephanie has also been active in different public-private partnerships in Real World Data, Epidemiology and Signal Detection: big data initiatives to develop the methods for web-based signal detection and several IMI (European Innovative Medicine Initiative) projects, including PROTECT for improvement of pharmacoepidemiology methods, WEB-RADR for signal detection methods using social media, PREFER on patients preferences and ConcePTION for safety of drugs in pregnant women where she is the industry lead of WP5 on dissemination and education.



Scott Evans
***Professor and Founding Chair**, Department of Biostatistics and Bioinformatics, Milken Institute School of Public Health, George Washington University, USA*

Dr. Scott Evans is a Professor and Founding Chair of the Department of Biostatistics and Bioinformatics and the Director of the Biostatistics Center at Milken Institute School of Public Health of the George Washington University. He is the: Director of the Statistical and Data Management Center for the Antibacterial Resistance Leadership Group (ARLG) funded by NIAID/NIH; the PI of the Coordinating Center for the Exercise and Nutrition Interventions to Improve Cancer Treatment-Related Outcomes (ENICTO) in Cancer Survivors Consortium funded by the NCI/NIH, and the co-PI of the Data Coordinating Center of the Clamp OR Delay among neonates with Congenital Heart Disease (CORD-CHD) clinical trial funded by the NHLBI/NIH. He served as: the Guest Editor of a mini-Series on DSMBs for the NEJM Evidence; a member of an FDA Advisory Committee; and the past-President of the Society for Clinical Trials (SCT). He is a recipient of the Mosteller Statistician Award, the Zackin Distinguished Collaborative Statistician Award, the Founders Award from the American Statistical Association (ASA), an elected member of the International Statistical Institute (ISI), and is a Fellow of the ASA, SCT, and the Infectious Disease Society of America (IDSA).

Claudia Ana Ianos
***Safety Risk Lead**, Pfizer, USA*

Ana-Claudia Ianos, MD, is Senior Director, Safety Risk Lead in Worldwide Safety at Pfizer, responsible for proactive safety surveillance and lifecycle benefit-risk management for drugs and vaccines in various stages of development. Claudia is a medical doctor with over 15 years of experience in global pharmacovigilance in biopharmaceutical industry. Her focus is the development and implementation of innovative safety and benefit risk strategies for complex projects involving high uncertainties or safety issues of public health impact. She is the safety Co-chair of the Pfizer Benefit Risk Advisory Council, and a member of the CIOMS Working Group XII on Benefit Risk Assessment for Medicinal Products.

Shahrul Mt-Isa
***Senior Director, BARDS HTA Statistics**, MSD, Switzerland*

Shahrul Mt-Isa, PhD is Senior Director in the Health Technology Assessment (HTA) Statistics group within the Biostatistics and Research Decision Sciences (BARDS) organisation at MSD, based in Zurich, Switzerland. As Therapeutic Area Head, he oversees the global vaccines portfolio, guiding the company's HTA/NITAG engagement and reimbursement strategies. Dr. Mt-Isa leads a small team of statisticians, supervises postdoctoral researchers and interns, and coordinates research initiatives spanning across benefit-risk assessment (BRA), survival modelling, treatment switching, indirect comparisons, and patient-reported outcomes – advancing methodologies crucial to HTA.

Prior to joining MSD, Dr. Mt-Isa was an academic statistician at Imperial College London's School of Public Health, where he contributed to clinical trials and BRA research, notably serving as Deputy Public Lead for the IMI-PROTECT project. He remains committed to academic excellence as Methodology Pillar Lead within BARDS HTA Statistics. Externally, Dr. Mt-Isa co-chairs the EFSPI/PSI BRA European Special Interest Group (ESIG) and member of the HTA ESIG, represents MSD on the CIOMS XII Working Group on BRA, and actively contributes to several international scientific working groups, shaping the future of HTA and statistical innovation.