Hilton Baltimore Inner Harbor

Jan 27, 2025 7:30 AM - Jan 29, 2025 12:45 PM

401 W Pratt Street, Baltimore, MD 21201, USA

Global Pharmacovigilance and Risk Management Strategies Conference

Stay current with the latest safety regulations from global health authorities and regulatory experts!

REGISTER →

Early Bird Rates End

09	22	58	36
DAYS	HOURS	MINUTES	SECONDS

Print Agenda

Day 1 Jan 27, 2025

7:30 AM — 5:00 PM

Conference Registration

7:30 AM — 8:30 AM

Networking Breakfast

8:30 AM — 8:45 AM

Welcome and Opening Remarks

Speaker(s)

Welcome and Opening Remarks

Sorcha McCrohan, MS

Scientific Projects Manager
DIA, United States

Sorcha McCrohan is a Specialist of Scientific Programs for the Americas Region at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines Meningococcal franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

Welcome and Opening Remarks

James Buchanan, PharmD

President
Covilance LLC, United States

Dr. James Buchanan is presently an independent drug safety consultant. Dr. Buchanan began his industry career at Genentech where he worked for 9 years in the areas of medical information and drug safety. He subsequently established the drug safety departments at Gilead, Tularik and Nuvelo. Dr. Buchanan next served at BioSoteria as the head of the medical and safety consulting group. Dr. Buchanan is currently president of Covilance, LLC, a drug safety consulting service. He is also a co-lead of the American Statistical Association Biopharmaceutical Safety Working Group Interactive Safety Graphics taskforce that is developing novel, open-source interactive graphical tools to identify and evaluate safety issues during drug development.

Welcome and Opening Remarks

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Worldwide Safety Officer
Bristol-Myers Squibb Company, United States

Mariette Boerstoel-Streefland, MD, MBA, MSc(epi), has been in the pharmaceutical industry for 30 years, and is currently SVP, Worldwide Patient Safety Officer at BMS. Mariette joined pharma industry from clinical practice in

1989 and held various leadership positions in drug safety at Organon (now Merck), Mayne Pharma (now Hospira/Pfizer), Forest Labs (now Abbvie). In 2014 she joined Baxter to establish a new safety organization for Baxalta, and upon the acquisition by Shire led the new combined safety organizations. In 2018 she moved to Alexion and with the acquisition by AZ was appointed Chief Safety Officer, SVP Global patient safety. In August 2023 she joined BMS. Mariette has an MD degree from the University of Utrecht, a MSc Pharma

8:45 AM — 9:30 AM

Session 1: Keynote Address

Session 1: Keynote Address

Session Chair(s)

James Buchanan, PharmD

President
Covilance LLC, United States

Dr. James Buchanan is presently an independent drug safety consultant. Dr. Buchanan began his industry career at Genentech where he worked for 9 years in the areas of medical information and drug safety. He subsequently established the drug safety departments at Gilead, Tularik and Nuvelo. Dr. Buchanan next served at BioSoteria as the head of the medical and safety consulting group. Dr. Buchanan is currently president of Covilance, LLC, a drug safety consulting service. He is also a co-lead of the American Statistical Association Biopharmaceutical Safety Working Group Interactive Safety Graphics taskforce that is developing novel, open-source interactive graphical tools to identify and evaluate safety issues during drug development.

Speaker(s)

Keynote Speaker

Representative Invited

Harvard Medical School, United States

Panelist

Representative Invited

Multiple Myeloma Research Foundation, United States

9:30 AM — 10:15 AM

Networking Break in Exhibit Hall

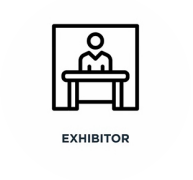
9:35 AM — 10:05 AM

Hosted Session/Non-CE: Case Study Sponsored by RxLogix

How adopting a harmonized, unified, and integrated PV Platform consolidates various systems into a cohesive solution, leading to increased efficiency, cost savings, scalability, enhanced security, and improved collaboration?

- Streamlined Operations
- Enhanced Data Transparency and Accessibility
- Efficiency and Productivity
- Improved Data Quality and Accessibility
- Regulatory Compliance and Reporting
- Cost Reduction
- Scalability and Flexibility
- AI and Automation- Minimal Manual Work

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

How does A harmonized, unified, and integrated platform enhance pharmacovigilance processes, and what are the key benefits?

Raj More

CEO and Chief Architect
RxLogix Corporation, United States

10:15 AM — 11:30 AM

Session 2: Regulatory Updates on Polices and New Guidances from Other Territories and International Harmonization

The session will provide updates on pharmacovigilance and risk management in countries of Asia region and how we comply with local specific requirements in those rapidly evolving environments. The focus this year will be describing pharmacovigilance requirements in India, some updates in China and Japan, and comparison of Pharmacovigilance System Master File requirements in Asia.

Learning Objective :

- Understand the overview of regulatory requirements for drug safety in the Middle East and African countries and key challenges
- Recognize the high-level overview of TransCelerate PV initiatives update and global harmonization activities

Session Chair(s)

Mamiko Kasho

Executive Director, Global PV Management Dept., Global Safety HQs
Eisai Co., Ltd., Japan

Mamiko Kasho is Executive Director of Global Pharmacovigilance Management in Global Safety HQ of Eisai Co., Ltd, and has been involved in global PV area since she joined the company in 2007. Mamiko has been responsible for PV agreements with licensing partners for 15 years and at the same time in charge of establishing, maintaining the quality management system in PV; and continues working on coordinating activities to comply with regulatory requirements across regions. Mamiko has been participating in several task forces of JPMA PV committee as the team leader, focusing on PV requirements in Europe, US, Asia, and other regions. Mamiko is also the member of MedDRA Management Committee since Mar 2020 as the representative of JPMA.

Speaker(s)

Speaker

Andrew Bate, PhD, MA

Vice President, Head of Safety Innovation and Analytics
GlaxoSmithKline, United Kingdom

Andrew is VP and Head of Safety Innovation & Analytics at GSK and a member of the Global Safety Leadership team. Previously Andrew was in the Epidemiology Leadership team at Pfizer for a decade. Prior to joining Pfizer, Andrew was at the Uppsala Monitoring Centre for more than 12 years, where he led the Research function. Andrew has over 100 publications on AI RWE and signal detection and has participated in several international initiatives in the area. Andrew is Honorary Associate Professor of Epidemiology at LSHTM.. Andrew has and does contribute to several international initiatives and has been a member of the Transcelerate PV Steering Committee since 2020 and sponsor for several Transcelerate workstreams.

11:30 AM — 12:30 PM

Networking Luncheon in the Exhibit Hall

12:30 PM — 1:45 PM

Session 3: Updates on Polices, Guidances and Regulations – United States (U.S. Food and Drug Administration (USFDA)

This session will provide key updates from the Office of Surveillance and Epidemiology (OSE) within the Center for Drug Evaluation and Research (CDER). It will focus on the REMS Integration Project Use Case and how it incorporates participant community feedback to inform iterative updates to the REMS integration prototype and present future updates to the REMS integration data standard. Additionally, the session will include an overview of the FDA's draft Guidance on the REMS Logic Model, a framework designed to link REMS program design with assessment, offering valuable insights for the industry.

Learning Objective :

- Identify advances in FDA pharmacovigilance and risk management strategies, including REMS
- Describe recent REMS Integration Use Case and Prototype Updates, discuss the importance of the REMS data standard (HL7® US Medication REMS FHIR® Implementation Guide) publication, and describe the future vision for REMS integration with data standards
- Explain the purpose of FDA's draft guidance and describe the three phases of the REMS logic model

Session Chair(s)

Scott Janiczak, PharmD, MPH

Safety Evaluator, LCDR, Division of Pharmacovigilance I, OSE, CDER
FDA, United States

Scott Janiczak a Lieutenant Commander (LCDR) in the U.S. Public Health Service, who serves as a safety evaluator in the Office of Surveillance and Epidemiology's, Division of Pharmacovigilance at FDA. In this role, he works with multidisciplinary scientific review teams throughout the FDA to evaluate adverse drug events detected during postmarketing surveillance activities. Prior to this position, he served as a regulatory project manager with the FDA's, Office of Generic Drugs for 6 years. LCDR Janiczak obtained his Doctor of Pharmacy from Midwestern University and holds a national board certification in Pharmacotherapy from the Board of Pharmacy Specialties.

Joseph Paradis, PharmD

Associate Director for Medication Error and Risk Management Initiatives, CDER
FDA, United States

Joe obtained his BS degree in Pharmacy at Rutgers in 1983 and initially worked in clinical research in the pharmaceutical industry. After 10 years he obtained his PharmD at the University of Maryland. Since then he has had extensive experience in pharmacy benefits management, as a consultant pharmacist, and clinical pharmacy practice. Joe joined the FDA as a REMS assessment analyst in June of 2020 and has been the lead reviewer of assessment reports, methodology submissions, and assessment plan development for several REMS Programs. In July 2023 he transitioned to Associate Director of Medication Error and Risk Management Initiatives within the Office of Medication Error Prevention and Risk Management.

Speaker(s)

Updates From the Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER)

Representative Invited

FDA, United States

Gerald J. Dal Pan, MD, MHS currently serves as the Director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the Center's programs in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act and other initiatives.

REMS Integration and Innovation Project Update

Edward D. Millikan, PharmD, RPh

Senior Clinical Informatics Pharmacist, OMEPRM, OSE, CDER
FDA, United States

Ed Millikan, PharmD, is the Senior Clinical Informatics Pharmacist in the Office of Surveillance and Epidemiology (OSE), within FDA's Center for Drug Evaluation and Research. He has over 25 years of experience with healthcare terminologies (e.g., NLM RxNorm, SNOMED CT) and data standards (e.g., NCPDP SCRIPT, HL7® FHIR®), REMS interoperability, and coding. Dr. Millikan currently serves as a champion for the HL7® CodeX® REMS Integration Use Case and is a co-lead for the HL7® Vulcan® Adverse Event project. Dr. Millikan graduated magna cum laude from the Campbell University School of Pharmacy and completed a residency in Drug Information and Pharmaceutical Informatics at the University of California, San Francisco and First Databank.

A Review of the FDA's Draft Guidance: Risk Evaluation and Mitigation Strategies (REMS) Logic Model

Victoria Sammarco, PharmD, MBA

Risk Management Analyst
FDA, United States

Victoria Sammarco, PharmD, MBA is a Risk Management Analyst in the Division of Risk Management in the Office of Surveillance and Epidemiology at FDA. As a Risk Management Analyst, she has worked on the design, implementation and evaluation of Risk Evaluation and Mitigation Strategies (REMS) for drugs in a variety of therapeutic areas, as well as in REMS modernization efforts. Previous to this role, she practiced at the Johns Hopkins Hospital for over ten years, serving in range of roles supporting medication safety for children and adults. She received a PharmD and MBA from the University of Maryland/University of Baltimore in 2012 and 2013, respectively.

1:50 PM — 3:05 PM

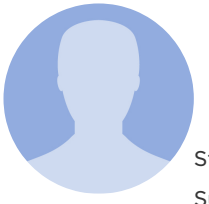
Session 4: Europe and United Kingdom: Regulatory Updates on Policies and Guidances

This session will provide the latest updates on pharmacovigilance and risk management in Europe and the United Kingdom, with an emphasis on navigating local regulatory requirements in these rapidly changing landscapes. Key topics will include MHRA's new pharmacovigilance guidance following the Windsor Framework agreement, changes to GVP Module XVI Rev III and its appendix on effectiveness measurement, and the introduction of CIOMS XII guidelines on benefit-risk assessment. The speakers will also discuss how these updates are set to drive improvements in benefit-risk planning and management, particularly through enhanced cross-functional collaboration and early-stage planning.

Learning Objective :

- Discuss MHRA's new pharmacovigilance guidance following the Windsor Framework agreement and its implications for compliance and risk management
- Review the updates to GVP Module XVI Rev III and its appendix on effectiveness measurement, focusing on their impact on current practices

Session Chair(s)



Representative Invited

MHRA, United Kingdom

Stephanie is Head of the Immunology, Biocompatibility and Non-clinical team in the Safety and Surveillance group at the MHRA. Prior to her current role she held a variety of management and assessor positions in the Agency. She has a masters degree in Clinical Pharmacology and a PhD in Cell Biology. She joined the Agency following a career in academia and has now over 20 years experience in drug regulation with particular experience in post-authorisation procedures and pharmacovigilance.

Speaker(s)

GVP Guideline

Representative Invited

European Medicines Agency, Netherlands

Since joining EMA in 2006, Thomas Goedecke has worked in all major areas of pharmacovigilance. His roles encompassed data collection and management in EudraVigilance, risk management for authorized medicines, with a focus on medication errors. Since 2015, he spearheads the implementation of the PRAC Impact Strategy,coordinating impact assessments and regulatory research for the European medicines regulatory network. He has contributed to the ENCePP Methods Guide and GVP guidelines on RMM effectiveness evaluation. Additionally, he oversees medication error reporting guidelines.

Speaker

Priya Bahri, PhD, RPh

Senior Lead (Pharmacovigilance and Risk Management Guidance and Policy)
European Medicines Agency, Netherlands

Priya Bahri, RPh, PostGradDipEpi, PhD, at EMA since 1996, is now EMA's Lead Pharmacovigilance and Risk Management Guidance and Policy. In this role, she also instigates research and regulatory frameworks for risk communication, stakeholder engagement for pharmacovigilance and implementation of risk minimisation in healthcare. Pro bono, she is active in the learned societies ISoP and ISPE and as associated researcher at Utrecht University. She is the editor of the Springer textbook "Communicating about Risks and Safe Use of Medicines - Real Life and Applied Research", published in 2020.

QPPVs

Representative Invited

Castle Pharmacovigilance Ltd, United Kingdom

Elspeth McIntosh began her career in the pharmaceutical industry in 1993, initially working in clinical research, before moving into Pharmacovigilance. She has extensive experience of all aspects of pharmacovigilance and has been a small company QPPV since 1999, dealing with innovative, generic and biotech/biological products. Elspeth set up Castle Pharmacovigilance in 2009 and post Brexit she is a UK QPPV and UK National Contact Person for several small pharma companies and provides general PV support to a wide range of pharma companies.

3:05 PM — 3:45 PM

Networking Break in the Exhibit Hall

3:10 PM — 3:40 PM

Hosted Session/Non-CE: Case Study Sponsored by APCER

3:45 PM — 5:00 PM

Session 5: Real-World Evidence in Action: Bridging Data for Regulatory Decisions and Drug Safety

The growing role of Real-World Evidence (RWE) in the regulatory landscape is reshaping how drug safety and efficacy are assessed. This session will explore the strategic integration of RWE in regulatory submissions and post-marketing commitments, focusing on case studies and success stories that demonstrate successful utilization of RWE across various stages of the drug development lifecycle. Speakers will discuss the practical implications of the FDA's guidance, "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products." Emphasis will be on best practices for utilizing EHRs and claims data. The session also addresses RWE's role in pharmacovigilance, enhancing drug safety monitoring and proactive risk management.

Learning Objective :

- Understand the regulatory landscape: Examine the key considerations and requirements for utilizing RWE in regulatory submissions, including best practices for data quality, integrity, and alignment with regulatory standards
- Apply FDA guidance effectively: Gain insights into leveraging the FDA's latest guidance on EHRs and medical claims data, ensuring compliance and maximizing the value of RWE in regulatory decision-making

Session Chair(s)

Tarek Hammad, MD, PhD, MS, MSc, FISPE

Vice President, Head of Medical Safety, Marketed Products & Plasma-Derived Thera
Takeda, United States

Dr. Tarek Hammad, VP & Head of Medical Safety for Marketed Products at Takeda Pharmaceuticals, is a renowned expert in drug safety, benefit-risk assessment, and pharmacoepidemiology. With extensive experience at major pharmaceutical companies like Sanofi and Merck, as well as a distinguished 13-year career at the US FDA, he has received numerous awards for his contributions. Dr. Hammad is a sought-after speaker, actively involved in industry initiatives and has held several academic appointments. He has authored over 80 peer-reviewed articles, book chapters, and letters to the editor, offering valuable insights in the field. Learn more at www.DrTarekHammad.com.

Speaker(s)

Practical Application of FDA Guidance on RWE Including Regulatory Expectations for RWE Quality

Representative Invited

FDA, United States

Dr. Marie Bradley is a Senior Advisor on the Real-World Evidence Analytics team in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), FDA. Her responsibilities related to real-world evidence (RWE) include serving as technical lead for externally conducted RWE demonstration projects, evaluating real-world evidence protocols, participating in internal Agency processes, interacting with stakeholders, and contributing to guidance development. She is a pharmacoepidemiologist and a pharmacist with over 14 years of experience working in regulatory, government, and academic sectors in UK and the US, including 10 years at the FDA.

Case Study: Successful Integration of RWE in Label Expansion

Representative Invited

European Medicines Agency, Netherlands

Luis Correia Pinheiro is a Senior Epidemiology Expert at the Data Analytics and Methods Taskforce, Real World Evidence Workstream, in the European Medicines Agency, where he designs and conducts real-world data studies and works on digital methods development. He also coordinates the Health Data Lab at the European Medicines Agency and has several functions related to enabling the safe and responsible use of AI with healthcare data, including RWD. He has worked in the field of pharmacovigilance and drug safety for over 22 years, in academic and regulatory settings.

Interplay of Adverse Events Spontaneous Reporting and Longitudinal Electronic Health Records for Signal Management

Representative Invited

Harvard Medical School, United States

Dr. Maro is an Assistant Professor in the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. She received her doctorate in Engineering Systems at the Massachusetts Institute of Technology (MIT). She is also the Operations Lead for the Sentinel Operations Center (housed at Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute) as part of the U.S. Food and Drug Administration's Sentinel System. The Sentinel Operations Center is responsible for the coordination of data curation, management, and utilization activities among multiple data partner sites covering data on several hundred million patients.

Overcoming Barriers to Using RWE in Post-Marketing Surveillance

Representative Invited

FDA, United States

CAPT Monica Muñoz is the Director of the Division of Pharmacovigilance-I within US FDA's Center for Drug Evaluation and Research. Since joining FDA in 2010, she has served as a safety reviewer, managed review teams, and provided oversight for pharmacovigilance initiatives. Her research interests have centered on better understanding postmarketing adverse event data, signal identification methodologies, and leveraging data science tools for surveillance. CAPT Muñoz also serves as a pharmacy officer in the US Public Health Service and has deployed for various missions, including in response to the Ebola epidemic in West Africa and most recently for COVID-19.

5:00 PM — 6:00 PM

Networking Reception

Day 2 Jan 28, 2025

7:30 AM — 5:00 PM

Conference Registration

7:30 AM — 8:00 AM

Networking Breakfast

8:00 AM — 10:30 AM

Session 6 and 7: Global Convergence in Risk Management Guidance Driving New Innovation Opportunities (Part I and Part II)

The session will review the current state of the art in REMS and aRMMs, review, and highlight the convergence of, the most recent and relevant guidance updates from FDA, EMA and CIOMS and propose new ways of collaborative working for the industry to build on the regulatory drivers and provide better support for patients.

Learning Objective :

- Describe the key guidance updates that impinge on management of risk
- Discuss the key areas in which the expectations of global regulators are converging
- Construct new operating models that will build on the regulatory approaches and drive better patient outcomes

Session Chair(s)

Mark Perrott, PhD

Managing Partner
Axian Consulting Ltd., United Kingdom

Mark is a founder and managing partner at Axian Consulting, where he focuses on improving benefit-risk balance and outcomes for patients through improving communication and adding value using digital approaches. He has a >20 year pharma career which has included industry (Wellcome, GW, GSK and AZ) and consultancy roles (WCI, Foresight, PopeWoodhead, Huron and now is a founder and managing partner of Axian Consulting). He is now focusing on the opportunities presented by improved benefit-risk management approaches to enhance risk management decision-making in development and on adding value to the interactions of industry and customers to maximise B-R balance and improve outcomes in REMS and aRMM programmes.

Ranjeeta Sinvhal, MD

Executive Medical Director, Medical Safety
AbbVie, United States

Extensive experience in both post-marketing and pharmacovigilance in clinical trials for over 19 years. In-depth global filing experience as a safety lead for both small molecule and biologics. Instructor in Loyola PV Certificate Course. Co-chair of Cardiovascular Internal Safety Advisory Group at AbbVie. Member of DIA ASA Safety WG (workstream 3). Intimate knowledge of processes and regulations in ICSR, aggregate reporting and signal detection. Current knowledge of PV regulations including EU good pharmacovigilance practices. Comprehensive and current knowledge of Internal Medicine (current Board certification). Comprehensive knowledge of drug development process and conduct and reporting of post authorization.

Speaker(s)

Risk Management in the United States – A Focus on Risk Evaluation and Mitigation Strategies (REMS)

Siobhan Duffy, MS, RPh

Associate Director, REMS Strategy & Submissions
Bristol Myers Squibb, United States

Overview of Current Approaches to Improve Risk Management Decision-Making, Build Tools that Work for Key Stakeholders and Capture Real-Time Data to Support Evaluation

Michael Forstner, PhD, MPH, MSc

Head of Global Safety Science
SOBI, Switzerland

Michael's main focus areas are the planning, development, implementation and evaluation of benefit-risk management solutions, as well as the optimization of processes around signal and benefit-risk management. He is engaged in developing and applying (benefit-) risk analysis and signal management methodologies in order to make RM planning more formally reproducible. Furthermore, he supports the development, implementation and evaluation of effectiveness of additional risk minimization and PV measures in the context of RMPs, as well as post-authorization studies to optimize the benefit-risk profiles of medicines.

Convergence of EU GVP, US REMS Guidance and CIOMS XII. Opportunities to Strengthen Industry Decision Making, Build Integrated Systems to Support Risk Management and Take a More Global Approach

Jamie Wilkins, PharmD

Head- Risk Management Center of Excellence
Pfizer Inc, United States

Jamie Wilkins, Pharm.D. is an experienced pharmacist and former regulator currently responsible for partnering with internal and external stakeholders on delivering innovative, strategic global safety and risk management excellence for Pfizer's drug and biologics portfolio. Prior to her role at Pfizer, Jamie served as the Deputy Director for the Division of Risk Management (DRM) at the US FDA. She is a two-time recipient of the FDA Francis O. Kelsey drug safety award, and has a deep passion for safety, and risk management science. Jamie earned her Doctor of Pharmacy degree in 2008 from the University of Maryland School of Pharmacy, and in her free time, enjoys spending time with her children and watching softball.

Implications on Approaches to Risk Minimization Effectiveness Measurement of the New EMA GVP XVI Rev III Guidance, the Addendum on Effectiveness Measurement and the FDA Logic Model

Representative Invited

GSK, United Kingdom

Rob Massouh, is the Head of Safety (PV) Risk Management and Benefit-Risk Evaluation at GSK. In this role, he serves as the subject matter expert in risk management strategy and benefit-risk evaluation. Rob was previously at the MHRA working as a Scientific Assessor within the Benefit Risk Management Group. Rob is a registered Pharmacist and received his MPharm at the University of Manchester.

Ongoing Initiatives to Define how a Digital Approach can Support the Achievement of Risk Minimization Objectives

Priya Bahri, PhD, RPh

Senior Lead (Pharmacovigilance and Risk Management Guidance and Policy)
European Medicines Agency, Netherlands

Priya Bahri, RPh, PostGradDipEpi, PhD, at EMA since 1996, is now EMA's Lead Pharmacovigilance and Risk Management Guidance and Policy. In this role, she also instigates research and regulatory frameworks for risk communication, stakeholder engagement for pharmacovigilance and implementation of risk minimisation in healthcare. Pro bono, she is active in the learned societies ISoP and ISPE and as associated researcher at Utrecht University. She is the editor of the Springer textbook "Communicating about Risks and Safe Use of Medicines - Real Life and Applied Research", published in 2020.

The Opportunities of AI in REMS and aRMM, Burden Reduction, Efficiency Improvement

Ramon Dempers

Founder/CEO
Invaryant Inc, United States

10:30 AM — 11:15 AM

Networking Break in the Exhibit Hall

10:35 AM — 11:05 AM

Hosted Session/Non-CE: Case Study Sponsored by IQVIA

11:15 AM — 12:30 PM

Session 8: Utility of AI in PV

After a more general overview of applicability of AI in PV, this session will share insights into what has emerged from the ongoing efforts in CIOMS XIV on the topic. After this, the audience will get deeper insights into two cases of successful leveraging of AI technology. The first is focused on increasing efficiency with literature review and case extraction, the second is on improved efficiencies in signal evaluation. This session is intended to increase understanding and stimulate thinking on where AI can help further our field of PV.

Learning Objective :

- Understand general principles of application of AI in PV
- Appreciate advantages and caveats
- Get deeper insights in what are and what aren't good use cases for AI application
- Increase ability to judge what AI application does and what doesn't make sense for their specific organization

Session Chair(s)

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Worldwide Safety Officer
Bristol-Myers Squibb Company, United States

Mariette Boerstoel-Streefland, MD, MBA, MSc(epi), has been in the pharmaceutical industry for 30 years, and is currently SVP, Worldwide Patient Safety Officer at BMS. Mariette joined pharma industry from clinical practice in 1989 and held various leadership positions in drug safety at Organon (now Merck), Mayne Pharma (now Hospira/Pfizer), Forest Labs (now Abbvie). In 2014 she joined Baxter to establish a new safety organization for Baxalta, and upon the acquisition by Shire led the new combined safety organizations. In 2018 she moved to Alexion and with the acquisition by AZ was appointed Chief Safety Officer, SVP Global patient safety. In August 2023 she joined BMS. Mariette has an MD degree from the University of Utrecht, a MSc Pharma

Speaker(s)

CIOMS Working Group XIV – Artificial Intelligence in Pharmacovigilance Representative Invited

FDA, United States

Updesh Dosanjh

Practice Leader, Technology Solutions
IQVIA, United States

As Practice Leader for Technology Solutions, Dosanjh is responsible for the overarching strategy regarding AI and Machine Learning as it relates to safety/pharmacovigilance. He focuses on the adoption of innovative technologies to help optimize pharmacovigilance activities for better, faster results. He has 25+ years of experience in the management, development, implementation, and operation of processes and systems within the life sciences and other industries. He has worked with WCI, Logistics Consulting Partners, Amersys

Systems Limited, and FJ Systems. He holds a Bachelor's degree in Materials Science from Manchester University and a Master's degree in Advanced Manufacturing Systems and Technology from Liverpool University.

Leveraging Intelligent Automation Improved Efficiency in Pharmacovigilance Signal Evaluation

Jeffrey Warner, PhD, MS

Post-Doctoral Scientist
Eli Lilly and Company, United States

I am a post-doctoral scientist in the Global Patient Safety organization within Eli Lilly supporting pharmacovigilance safety signal management through AI use case development. My prior doctoral research focused on the intersection between nutrition and alcohol-associated liver disease with a focus on bio-active lipid metabolites as exogenous therapies via in vivo models. In my current role, I've taken the lessons and strategies learned from the bench and applied them to PV science to enhance our ability and capacity to manage safety signals.

12:30 PM — 1:30 PM

Networking Luncheon and Roundtable Discussions in the Exhibit Hall

1:30 PM — 3:00 PM

Session 9: New Thinking Impacting Hepatic Drug Safety

Hepatotoxicity is a leading cause of drug development discontinuation as well as drug withdrawal from the market due to safety reasons. Consequently, the prediction, assessment and management of potential drug induced liver toxicity is critical. In addition, the safe use of drugs in patients with underlying liver disease is an important issue. This session will discuss new thinking related to the hepatic safety of drugs.

Learning Objective :

- Describe the FDA's Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program and the exploration of predictive organ-chip technology to screen for drug induced liver toxicity (DILI) potential
- Appraise different approaches to the assessment of hepatic safety data
- List regulatory challenges in DILI risk assessment

Session Chair(s)

Barbara Hendrickson, DrMed, MD

Clinical Associate, Pediatric Infectious Diseases
University of Chicago, United States

Dr. Barbara Hendrickson is a former Vice President of Pharmacovigilance and Patient Safety at AbbVie. She is currently on faculty at the University of Chicago. Dr. Hendrickson is a physician with subspecialty training in pediatrics and infectious diseases and has 19 years of pharmaceutical industry experience. Dr. Hendrickson has been involved in multiple new product and additional indication submissions. She also has participated in several clinical trial safety initiatives related to implementation of internal data monitoring committees and IND aggregate safety reporting procedures. In addition, she co-leads the DIA-ASA Aggregate Safety Assessment Planning Working Group.

Speaker(s)

Screening, Monitoring, and Managing of Hepatitis B Virus (HBV) Reactivation in Clinical Trials with Immunosuppressing or Immunomodulating Drugs

Arie Regev, MD

Vice President, Medical Global Patient Safety
Eli Lilly and Company , United States

Dr. Arie Regev is a gastroenterologist and hepatologist. He is a Vice President of Medical Global Patient Safety at Eli Lilly and Company. He heads Eli Lilly's Safety Advisory Hub and is the chair of Eli Lilly's Liver Safety Committee. Dr. Regev is an associate professor of medicine at the division of gastroenterology and hepatology of Indiana University School of Medicine. He was the co-chair of the CIOMS working group on Drug Induced Liver Injury (DILI) and was the co-author of the CIOMS consensus summary on DILI. Dr. Regev was the founding co-chair of the IQ-DILI initiative, and he currently co-chairs 3 of IQ DILI's working groups. He is the author of more than 150 publications and book chapters in major scientific journals and books.

Speaker

Representative Invited

FDA, United States

I am Associate Director for DILI at the FDA. I got my BA in microbiology at UCLA and MD at UC San Diego. After residency and gastroenterology training at UC Davis, I completed a research fellowship at the NIH and a transplant fellowship at the University of Colorado. I received an MPH at Saint Louis University, Missouri. In 2006, I became Medical Director of Liver Transplantation at the University of North Carolina serving in that capacity as associate and then full professor before joining the FDA in 2020. My research and publications have focused on drug-induced liver injury for the last 19 years. I was a Co-Investigator for the NIH Drug-Induced Liver Injury Network and remain Co-Chair of the Causality Committee.

Speaker

Representative Invited

Abbvie, United States

3:00 PM — 3:30 PM

Networking Break in the Exhibit Hall

3:30 PM — 5:00 PM

Session 10: Benefit Risk Assessment

Building on the foundation of the Benefit Risk Assessment session in the 2024 conference, this session on Benefit Risk Assessment in 2025 aims to further advocate for the adoption and implementation of early benefit/risk considerations in drug development, highlighting structured Benefit Risk Assessment and the deployment of decision-oriented visualization approach. The speakers will share real examples of how structured Benefit Risk Assessment might be implemented, and how to implement benefit risk considerations in protocol design and ongoing decision-making starting from early stage of clinical development. The speaker will also present decision-oriented visualizations to facilitate and drive early proactive discussions of what and how to assess benefit risk tradeoffs.

Learning Objective : At the conclusion of this session, participants should be able to:

- Apply and implement early benefit/risk considerations in earlier stage of drug development
- Follow structured Benefit Risk Assessment throughout the Clinical Development stage into post marketing
- Employ decision enhanced visualizations to facilitate good decision making

Session Chair(s)

Mengchun Li, MD, MPA

Senior Director, Clinical Research, Infectious Disease
Merck & Co., Inc., United States

Dr. Mengchun Li is currently working at Merck & Co., Inc. as a Senior Director, Infectious Diseases. Prior to this, Dr. Li worked at TB Alliance and Janssen Pharmaceutical company (J&J) in Drug Safety and Pharmacovigilance, Clinical Development, and Medical Affairs. Dr. Li is now co-leading the DIA-ASA (American Statistical Association) joint safety working group fostering interdisciplinary collaboration to improve safety evaluation in drug development. Dr. Li received her MD from China Medical University and her Master of Public Administration from Columbia University.

Speaker(s)

Speaker

Leo Plouffe, MD

Head of Global Patient Safety
Gilead Sciences, United States

Structured Benefit-Risk Assessment in AstraZeneca

Representative Invited

AstraZeneca, United States

Day 3 Jan 29, 2025

7:30 AM — 12:45 PM

Conference Registration

7:30 AM — 8:00 AM

Networking Breakfast

8:00 AM — 9:15 AM

Session 11: Operations: Small vs. Big Pharma

Small biotech and pharma companies have unique challenges in building a pharmacovigilance framework that requires the right expertise at the right time. Often small companies are facing budgetary and resourcing struggles and have to consider the risk of poor planning decisions that could impact product acquisition or commercialization in the future. This session will take a deep dive into the specific challenges small pharma companies face and provide practical solutions for managing these unique issues.

Learning Objective :

- Define the specific challenges small pharma face with respect to building a pharmacovigilance framework
- Design a plan to establish the PV function at a small pharma
- Understand what is needed to demonstrate adequate oversight of PV vendors

Session Chair(s)

Bethany Van Veen

Pharmacovigilance Consultant
Perspective Pharmacovigilance, United States

Speaker(s)

Pharmacovigilance in a Startup Company – You're in charge, now what?

Representative Invited

Cross BioConsulting, United States

Speaker

Sylvia Dobo, MD

SVP, Global Drug Safety and Pharmacovigilance
Biocryst Pharmaceuticals, United States

Sylvia leads the safety team at BioCryst Pharmaceuticals, a small, rare disease biotech with globally marketed products and a clinical pipeline. She's worked in industry, both PV and clinical development, for over 20 years, being a lead contributor to 3 NDAs and several sBLAs. With the help of a great team, she built the BioCryst PV function from scratch. Previously, she was the US Head of Safety Knowledge and Reporting at Quintiles (now IQVIA), a Safety Lead at Genentech and Roche, and a Safety Physician at Abbott Laboratories (now AbbVie). Prior to industry, she practiced medicine and taught residents at the Fineberg School of Medicine, Northwestern University. She earned her BS and MD degrees from the University of Miami.

Speaker

Stephen Knowles

Vice President of Drug Safety Pharmacovigilance
Crinetics Pharmaceuticals, United States

9:20 AM — 10:35 AM

Session 12: Clinical Trials & Pharmacovigilance

This session will provide an introduction and overview of the newly-released FDA Draft Guidance on Use of Data Monitoring Committees (DMC) in clinical trials. Valuable practical information will be provided to enable safety professionals to better evaluate DMC charters and support the implementation of DMCs. In addition, the potential use of DMCs in IND reporting decisions for anticipated events in the study population will be discussed.

Learning Objective :

- Understand the new FDA Draft Guidance published in Feb 2024, “Use of Data Monitoring Committees in Clinical Trials” (“DMC Draft Guidance”)
- Describe common misconceptions of DMCs and best practices for training of DMC members

Session Chair(s)

Susan Kindig, JD, MD

Prior Executive Director, Medical and Drug Safety
United States

Susan most recently led the patient safety department at Halozyme and supported both the medical and regulatory functions there from March, 2022 to January, 2024. Prior to joining Halozyme, Susan spent 10 years working in Global Patient Safety at Eli Lilly. She used her clinical experience as an OB/GYN while in pharma to aid in the initial stages of the ConcePTION project, as a working group member for PRGLAC, and most recently on a pregnancy-related TransCelerate project. Susan earned her MD from Indiana University and her JD from Indiana University School of Law – Indianapolis. She is currently starting a foundation to support camps for teens across the country who are interested in medicine.

Barbara Hendrickson, DrMed, MD

Clinical Associate, Pediatric Infectious Diseases
University of Chicago, United States

Dr. Barbara Hendrickson is a former Vice President of Pharmacovigilance and Patient Safety at AbbVie. She is currently on faculty at the University of Chicago. Dr. Hendrickson is a physician with subspecialty training in pediatrics and infectious diseases and has 19 years of pharmaceutical industry experience. Dr. Hendrickson has been involved in multiple new product and additional indication submissions. She also has participated in several clinical trial safety initiatives related to implementation of internal data monitoring committees and IND aggregate safety reporting procedures. In addition, she co-leads the DIA-ASA Aggregate Safety Assessment Planning Working Group.

Speaker(s)

Speaker

Representative Invited

FDA, United States

Speaker

Representative Invited

Duke Clinical Research Institute, Duke University Medical Center, United States

Frank is a full-time Professor of Biostatistics and Bioinformatics at Duke University Medical Center and Managing Partner of HunterRockhold, Inc., which provides strategic consulting to Industry and Government. His career includes senior positions at Lilly, Merck, and GlaxoSmithKline, where he retired as Chief Safety Officer. He has held faculty appointments at six different universities, served as Chairman of CDISC, and is past president of the Society for Clinical Trials. Frank holds a BA in Statistics and an ScM and PhD in Biostatistics. Frank is a Fellow of the American Statistical Association, The Royal Statistical Society, and the Society for Clinical Trials and is widely published across a wide variety of research topics.

10:35 AM — 11:15 AM

Networking Break in the Exhibit Hall

10:40 AM — 11:10 AM

Hosted Session/Non-CE: Case Study Sponsored by Truveta

11:15 AM — 12:30 PM

Session 13: Signal Detection

This session will cover several topics pertaining to the identification and evaluation of safety signals. One presentation will discuss a multimodal data product approach using a knowledge graph (KG) to enhance signal detection. FDA has previously released their FDA Medical Queries (FMQ) concept. Now PhUSE has published a best practices document for the use of adverse event term groupings that will be reviewed. Having then identified a safety signal, an evaluation is conducted to seek evidence supporting a causal relationship. The final presentation will review various methodologies for conducting a causality assessment.

Learning Objective :

- Describe how a Knowledge Graph integrates diverse structured and unstructured data sources for signal detection and its role in developing machine learning algorithms
- Understand the PhUSE recommendations for the use of AE term groupings in signal detection
- Assess the various approaches to considering evidence in support of a causal relationship between the drug and an adverse event

Session Chair(s)

James Buchanan, PharmD

President
Covilance LLC, United States

Dr. James Buchanan is presently an independent drug safety consultant. Dr. Buchanan began his industry career at Genentech where he worked for 9 years in the areas of medical information and drug safety. He subsequently established the drug safety departments at Gilead, Tularik and Nuvelo. Dr. Buchanan next served at BioSoteria as the head of the medical and safety consulting group. Dr. Buchanan is currently president of Covilance, LLC, a drug safety consulting service. He is also a co-lead of the American Statistical Association Biopharmaceutical Safety Working Group Interactive Safety Graphics taskforce that is developing novel, open-source interactive graphical tools to identify and evaluate safety issues during drug development.

Speaker(s)

Speaker

Representative Invited

MedAssessment, Inc., United States

Peg received her MD & PhD (biochemistry) from U Chicago and boards in Oncology and Clinical Pharmacology. A safety executive with over 25 years' experience in development and PVG in large and small pharma, Peg developed TAP Pharma's safety review process, led the protocol review team, and served on the Am Board of Clin Pharm. For the past 12 years she has led MedAssessment, a small PVG CRO focused on safety in early development.

Mutlimodal Safety Data products to enhance Signal Management and Detection

Sameen Desai, MBA, MS

Executive Director, IT Worldwide Patient Safety
Bristol-Myers Squibb Company, United States

Aspects to Consider in Causality Assessment of Safety Signals: Broadening the Thought Process

Tarek Hammad, MD, PhD, MS, MSc, FISPE

Vice President, Head of Medical Safety, Marketed Products & Plasma-Derived Thera
Takeda, United States

Dr. Tarek Hammad, VP & Head of Medical Safety for Marketed Products at Takeda Pharmaceuticals, is a renowned expert in drug safety, benefit-risk assessment, and pharmacoepidemiology. With extensive experience at major pharmaceutical companies like Sanofi and Merck, as well as a distinguished 13-year career at the US FDA, he has

received numerous awards for his contributions. Dr. Hammad is a sought-after speaker, actively involved in industry initiatives and has held several academic appointments. He has authored over 80 peer-reviewed articles, book chapters, and letters to the editor, offering valuable insights in the field. Learn more at www.DrTarekHammad.com.

12:30 PM — 12:45 PM

Closing Remarks

Speaker(s)

Sorcha McCrohan, MS

Scientific Projects Manager
DIA, United States

Sorcha McCrohan is a Specialist of Scientific Programs for the Americas Region at DIA. In her current role, she focuses on content development and strategy for DIA's meetings to improve and facilitate innovation in clinical research, drug development, and the fields of devices and diagnostics. Before joining DIA, she conducted COVID-19 research in Chiapas, Mexico, and worked in marketing within Pfizer's Global Vaccines Meningococcal franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.

James Buchanan, PharmD

President
Covilance LLC, United States

Dr. James Buchanan is presently an independent drug safety consultant. Dr. Buchanan began his industry career at Genentech where he worked for 9 years in the areas of medical information and drug safety. He subsequently established the drug safety departments at Gilead, Tularik and Nuvelo. Dr. Buchanan next served at BioSoteria as the head of the medical and safety consulting group. Dr. Buchanan is currently president of Covilance, LLC, a drug safety consulting service. He is also a co-lead of the American Statistical Association Biopharmaceutical Safety Working Group Interactive Safety Graphics taskforce that is developing novel, open-source interactive graphical tools to identify and evaluate safety issues during drug development.

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Worldwide Safety Officer
Bristol-Myers Squibb Company, United States

Mariette Boerstoel-Streefland, MD, MBA, MSc(epi), has been in the pharmaceutical industry for 30 years, and is currently SVP, Worldwide Patient Safety Officer at BMS. Mariette joined pharma industry from clinical practice in 1989 and held various leadership positions in drug safety at Organon (now Merck), Mayne Pharma (now Hospira/Pfizer), Forest Labs (now Abbvie). In 2014 she joined Baxter to establish a new safety organization for Baxalta, and upon the acquisition by Shire led the new combined safety organizations. In 2018 she

moved to Alexion and with the acquisition by AZ was appointed Chief Safety Officer, SVP Global patient safety. In August 2023 she joined BMS. Mariette has an MD degree from the University of Utrecht, a MSc Pharma

12:45 PM — 12:45 PM

Conference Adjourns