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!

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Print Agenda

Day 1 Jan 27, 2025

7:30 AM — 5:00 PM — East Foyer - 2nd Floor

Conference Registration

7:30 AM — 8:30 AM — Key Ballroom 1-6

Networking Breakfast

8:30 AM — 8:45 AM — Key Ballroom 7-12

Welcome and Opening Remarks

Speaker(s)

Welcome and Opening Remarks

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

Welcome and Opening Remarks

Sorcha McCrohan, MS

Scientific Project 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 Patient 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

Key Ballroom 7-12

Session 1: Keynote Address

Session 1: Keynote Address

Track: General Session

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)

The Power of Patients as a Vehicle for Change: A Patient's Perspective

Tiffany Studebaker-Freeman

Director of Operations and Finance

Paltown Development Foundation, United States

Tiffany Studebaker Freeman is the Director of Operations & Finance for PALTOWN Development Foundation, where she drives operational excellence and financial management for programs like COLONTOWN, an online community supporting over 13,000 colorectal cancer patients and caregivers across the globe. Previously, Tiffany was a small business owner, professional musician, and homeschooler to six children in the Appalachian Mountains of southwest Virginia, sharpening her skills in leadership, adaptability, and creativity. As a stage 3b colorectal cancer survivor of five years, Tiffany's personal experience fuels her passion for empowering others and inspiring hope, ensuring that no one faces colorectal cancer alone.

9:30 AM — 10:15 AM Key Ballroom 1-6

Networking Break in Exhibit Hall

9:35 AM — 10:05 AM East Foyer – 2nd Floor

Hosted Session/Non-CE: Case Study Hosted 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

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

How Does A Harmonized, Unified, and Integrated Platform Enhance Pharmacovigilance Processes, and

What are the Key Benefits of Consolidating Multiple Systems into a Single Solution?

Raj More

CEO and Chief Architect
RxLogix Corporation, United States

10:15 AM — 11:30 AM

Key Ballroom 7-12

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 :

- Describe the 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

Track: General Session

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)

PV Overview of Egypt

Representative Invited

Egyptian Drug Authority (EDA), Egypt

Shereen Abdelgawad is the Head of the Central Administration of Pharmaceutical Care at the Egyptian Drug Authority (EDA), with over 15 years of experience in pharmaceutical regulatory affairs and public policy. She holds master's degrees in Pharmaceutics & Industrial Pharmacy and Public Policy. Shereen focuses on improving pharmaceutical care practices, patient safety, and policies. She has spearheaded initiatives like e-labeling for accessible medical information and leads key committees on antimicrobial rational use and national guidelines. Her strategic leadership continues to drive advancements in pharmaceutical care and regulatory policy.

TransCelerate's Role in Global Pharmacovigilance Collaboration

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 is an Honorary Associate Professor of Epidemiology at LSHTM. Andrew has and does contribute to several international initiatives and has been a member of the Transcelerate Intergrated Leadership Team, and PV Steering Committee since 2020 and is sponsor/co-sponsor for several Transcelerate workstreams.

Update/Overview of Pharmacovigilance Regulatory Requirements in the Middle East and Africa

Zakaria Thamri, PharmD

Regional Patient Safety Lead - India, Middle East, Turkey and Africa
Boehringer Ingelheim, United Arab Emirates

Dr. Zakaria holds a Doctoral degree in pharmacy from Algeria and a Pharmacovigilance certificate from France. He started his career in Pharmacovigilance at Roche Pharmaceutical, where he has also served in different roles in Medical Affairs and Products Quality. Dr. Zakaria joined Boehringer Ingelheim in February 2019 as Pharmacovigilance Manager for the North-West Africa Region and is currently the regional Pharmacovigilance Lead for the IMETA region (India, Middle East, Turkey, and Africa) based in Dubai-UAE.

11:30 AM — 12:30 PM

Key Ballroom 1-6

Networking Luncheon in the Exhibit Hall

12:30 PM — 1:45 PM Key Ballroom 7-12

Session 3: Advancing PV: Industry Perspectives on FDA Updates, Risk Management, Data Standards, and Regulatory Alignment

Pharmacovigilance is fundamental to safeguarding public health and relies on a comprehensive approach that includes effective risk management, accurate safety reporting, regulatory oversight, and collaboration across stakeholders. This session highlights recent advancements in these areas, beginning with a presentation on FDA updates including REMS integration with data standards, and a review of the FDA Guidance on the REMS Logic Model as a framework for linking program design with assessment. Attendees will gain insights on the FAERS public dashboard and the transition to the ICH E2B(R3) standard with a focus on the implications of these advancements for data quality, consistency, and FDA oversight. The final presentation will address the complexities of safety labeling updates while highlighting the responsibility of pharmaceutical companies, the oversight of regulatory agencies, and the challenges of achieving alignment across global stakeholders.

Learning Objective :

- Identify advances in FDA pharmacovigilance and risk management strategies, including REMS
- Discuss the future vision of REMS integration with data standards, recent updates on REMS integration use cases and prototypes, and the significance of the REMS data standard publication
- Explain the purpose of FDA's draft guidance and describe the three phases of the REMS logic model

Track: General Session

Session Chair(s)

Sorcha McCrohan, MS

Scientific Project 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.

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Worldwide Patient 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)

Design and Implementation of Risk Minimization Measures Using REMS Logic Model – REMS Integration and Innovation

Lubna Merchant, PharmD, MS

Head, Risk Management Strategy
AbbVie, United States

Lubna is a Director in the Risk Management Center of Excellence at Pfizer, Inc., where she is responsible for the strategy and implementation of risk management plans globally. Dr. Merchant provides global leadership in delivering innovative and strategic risk management excellence, regulatory compliance, effectiveness evaluation, and operational excellence for Pfizer's portfolio of drug products with risk management programs. Prior to joining Pfizer, Dr. Merchant was the Deputy Director of the Office of Medication Error Prevention and Risk Management in FDA's Center for Drug Evaluation and Research's (CDER) where she was responsible for the Center's programs in risk management and medication error prevention.

Updates on the FAERS Public Dashboard and ICH E2B(R3) Implementation

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.

Achieving Synchrony: Bridging the Gap between Pharmaceutical Companies and Regulators on Safety Labeling Updates

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.

1:50 PM — 3:05 PM Key Ballroom 7-12

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 :

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

Track: General Session

Session Chair(s)

Stephanie Millican, PhD, MSc

Deputy Director Benefit Risk Evaluation, Safety and Surveillance
MHRA, United Kingdom

Stephanie is the Deputy Director of Benefit Risk Evaluation II 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)

Introduction to Ongoing and Upcoming EMA Pharmacovigilance Developments: What to Plan for in 2025 | Risk Minimisation Measures -GVP Module XVI and Addendum

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 Windsor Framework: A QPPV's Perspective

Elspeth McIntosh, MBA, RN

Director
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 Key Ballroom 1-6

Networking Break in the Exhibit Hall

3:10 PM — 3:40 PM East Foyer – 2nd Floor

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

Ensuring global compliance in pharmacovigilance (PV) and risk management at local level can be challenging because of the dynamic and complex regulatory landscape across multiple regions. Key challenges faced by global companies may include, but are not limited to, setting up local PV processes, including a local responsible person, regulatory intelligence, and a review of local literature and risk minimization measures in multiple languages, to ensure global oversight over local processes. Patient safety can be achieved by creating a harmonized PV system globally, respecting regional divergence with local PV activities performed as part of the global PV system. This should include setting up effective project management to ensure governance and local oversight at global level.

A case study will be discussed wherein APCER supported a global pharmaceutical company with multiple acquisitions and a diverse portfolio of products across multiple regions in successfully setting up a local PV and risk management system, ensuring global compliance.

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Local Pharmacovigilance and Risk management : An Important Puzzle to Solve for Global Compliance

Vineet Kacker, PhD

Managing Director & Global Technical Head
APCER Life Sciences Limited, United Kingdom

Dr. Kacker is a Pharmacologist by training, having completed his PhD in Pharmacology from All India Institute of Medical Sciences in India. Dr. Kacker switched his interests from academia to pharmaceutical industry more than 18 years ago, and has managed the Regulatory and Pharmacovigilance functions at global organizations. Dr. Kacker is a co-founder of APCER Life Sciences, having started the company out of UK more than 11 years ago. In his current role he operates as the Managing Director and Global Technical Head of APCER. Dr. Kacker has been a Qualified Person/Person Responsible for Pharmacovigilance with experience of more than 17 years as EU-QPPV and in his current role he does operate as the EU-QPPV for some of APCER's clients.

3:45 PM — 5:00 PM

Key Ballroom 7-12

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 key considerations for using RWE in regulatory submissions, including best practices for data quality, integrity, and alignment with regulatory standards
- Apply insights from FDA's latest guidance on EHRs and medical claims data to boost compliance and RWE's value in regulatory decision-making
- Analyze RWE's role in improveing drug safety monitoring and assess the benefits and challenges of integration in post-marketing safety commitments

Track: General Session

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)

Overview of the FDA Real-World Evidence Guidance

Samer El-Kamary, MD, MPH

Medical Director, Global Safety Lead
Takeda Pharmaceuticals Inc., United States

Dr. Samer El-Kamary is a Medical Director and Global Safety Lead at Takeda Pharmaceuticals, with expertise in epidemiology and drug safety. He brings a wealth of experience from his 14-year tenure as a tenured professor at the University of Maryland and a distinguished 5-year career at the U.S. FDA, where he received numerous awards for his contributions to drug safety, regulatory work, clinical research, education, and mentorship. Dr. El-Kamary has been an invited speaker at international conferences and academic institutions and has authored over 75 peer-reviewed articles, several book chapters and published abstracts. He is a licensed, board-certified pediatrician, and completed his fellowship and M.P.H. at the Johns Hopkins University.

Leveraging Multi-national Observational Studies in Post-marketing Safety Assessment

Judith Maro, PhD, MS

Associate Professor, Department of Population Medicine
Harvard Medical School, United States

Dr. Maro is an Associate 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 a site principal investigator for the U.S. Centers for Disease Control and Prevention's Vaccine Safety Datalink and also the Operations Lead for the Sentinel Operations Center 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.

5:00 PM — 6:00 PM | Key Ballroom 1-6

Networking Reception

Day 2 Jan 28, 2025

7:30 AM — 5:00 PM | East Foyer - 2nd Floor

Conference Registration

7:30 AM — 8:00 AM | Key Ballroom 1-6

Networking Breakfast

8:00 AM — 10:30 AM | Key Ballroom 7-12

Session 6 and 7 : Global Convergence in Risk Management Guidance Driving New Innovation Opportunities

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

Track: General Session

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 studies.

Speaker(s)

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

Siobhan Duffy, MS, RPh

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

I am pharmacist with 25 years of pharmaceutical industry experience in pharmacovigilance, medical information, scientific publications, but primarily in Risk Evaluation and Mitigation Strategies (REMS). I have worked as a consultant to pharmaceutical companies who need to develop a REMS program. I am currently working at Bristol Myers Squibb in REMS Strategy & Submissions overseeing several REMS programs.

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

Sherice R Mills

Head of US
Axian Consulting Ltd., United States

My love for patient safety has expanded over 17 years and continues to drive me today. Working with a passion for risk management and ensuring patients are armed with the tools they need to achieve the best results from their therapy is very important. Beginning my career in a lab as many of us scientists have done was instrumental in helping me carve out this niche area of interest in pharma. It gave me insights for this industry by allowing me to see the drug development process from beginning to end. As a chemical engineer in my early days in pharma, I learned about the importance of compliance and material handling for finished products and began to appreciate the need for safety measures throughout the life cycle of a product.

Considerations for Risk Management Decision-Making, Working with Key Stakeholders, and Implementation Science | Panelist

Michael Forstner, PhD, MPH, MSc

Managing Director, Head of Pharmacoepidemiology Practice
Mesa Laubela-Consulting, 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 | Panelist

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.

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 | Panelist

Robert Massouh, MPharm, RPh

Head of Safety (PV) Risk Management and Benefit/Risk Evaluation
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 | Panelist

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 | Panelist

Ramon Dempers, MSc

Founder/CEO
Invaryant Inc, United States

Ramon Dempers, Founder and President of Invaryant Inc., brings over four decades of expertise in engineering, business, and technology, with the last two plusdecades dedicated to healthcare innovation. With a background that spans leadership roles at Sun Microsystems, IBM Global Services, and the successful founding of three start-ups, Dempers has been instrumental in pioneering technologies that improve patient safety, access, and affordability in healthcare. A thought leader and advocate for patient empowerment, he has developed and patented AI-driven technologies and collaborated with leading institutions to tackle patient safety. Dempers is a globally recognized speaker on ethics in AI and life science and health IT innovation.

10:30 AM — 11:15 AM Key Ballroom 1-6

Networking Break in the Exhibit Hall

10:35 AM — 11:05 AM East Foyer – 2nd Floor

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

In this session, you will explore the compelling benefits for pharmaceutical companies in combining human expertise with advanced technology to optimize pharmacovigilance operations. Learn how integrating human insights with cutting-edge tools, including AI and machine learning, pharma companies can achieve greater efficiency, accuracy, and compliance in their safety monitoring processes. Explore real-world examples and industry research to demonstrate the practical applications and benefits of these integrated solutions in enhancing pharmacovigilance operations.

Learning Objective :

- Streamlining workflows, reducing manual effort, and speeding up processing
- Enhancing accuracy of detection and ensuring regulatory compliance
- Reducing operational costs and improving resource allocation
- Supporting experts with advanced analytics and visualization tools
- Exploring future advancements in AI and machine learning

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Optimizing Pharmacovigilance: Augmenting Human Expertise with Advanced AI/ML Technology

Archana Hegde

Senior Director, PV Systems & Innovations, Lifecycle Safety
IQVIA, United States

11:15 AM — 12:30 PM

Key Ballroom 7-12

Session 8: Harnessing AI in Pharmacovigilance: Insights, Applications, and Impact

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 :

- Discuss general principles of application of AI in PV
- Recognize advantages and caveats of AI in PV
- Identify what are and what aren't good use cases for AI application
- Examine how to increase ability to judge what AI application does and what doesn't make sense for their specific organization

Track: General Session

Session Chair(s)

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Worldwide Patient 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

Taxiarchis Botsis, PhD, MSc

Associate Professor of Oncology
Johns Hopkins University, United States

Harnessing Generative AI for Enhanced Literature Case Extractions in Pharmacovigilance

Uwe Peter Trinks, PhD, MS

Global Practice Lead, IQVIA
IQVIA, United States

Dr. Uwe Trinks, Global Practice Lead, PV Technology at IQVIA serves as Drug Safety and Risk Management Subject Matter Expert with over 32 years of life sciences experience. Prior to joining IQVIA, he served as Partner and Director of Foresight Group International for 10 years and as CIO of Sentrx for 10 years. Prior to that, he served as the Executive Director and Head of Research Information Management USA for Novartis. Dr. Trinks earned a M.S. in Organic and Natural Products Chemistry, and a Ph.D. in Organic Chemistry from the Federal Institute of Technology (ETH) in Zurich, Switzerland. He has also completed Postdoctoral Research in Biochemistry at Stanford 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 Key Ballroom 1-6

Networking Luncheon and Roundtable Discussions in the Exhibit Hall

1:30 PM — 3:00 PM Key Ballroom 7-12

Session 9: Advancing Hepatic Safety: Innovations in Predicting, Assessing, and Managing Drug-Induced Liver Toxicity

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 FDA's ISTAND Pilot Program and its role in advancing innovative science and technology, including applying predictive organ-chip technology to assess drug-induced liver toxicity (DILI) potential
- Appraise different approaches to the assessment of hepatic safety data
- List regulatory challenges in DILI risk assessment

Track: General Session

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 20 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 aggregate safety assessment plans, internal data monitoring committees, and IND aggregate safety reporting procedures. In addition, she co-leads Workstream One of the American Statistical Association's Biopharma Safety Working Group.

Speaker(s)

Hepatitis B Virus 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.

DILI in the Elderly

Eric B Cohen, MD

Senior Medical Director
Abbvie, United States

Dr. Cohen is a Senior Medical Director in Pharmacovigilance at AbbVie Inc. and has served as Chair of AbbVie's Liver Internal Safety Advisory Group (ISAG) since 2017. He completed a Gastroenterology and Hepatology fellowship at Yale-New Haven Medical Center in 2009 and an Advanced fellowship in Transplant Hepatology at Beth Israel Deaconess Medical Center-Boston in 2010. He is a subject matter expert in Drug-induced liver injury (DILI).

3:00 PM — 3:30 PM Key Ballroom 1-6

Networking Break in the Exhibit Hall

3:30 PM — 5:00 PM Key Ballroom 7-12

Session 10: Enhancing Drug Development with Early Benefit-Risk Strategies and Decision-Driven Visualizations

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
- Discuss how to follow structured Benefit Risk Assessment throughout the Clinical Development stage into post marketing
- Employ decision enhanced visualizations to facilitate good decision making

Track: General Session

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)

Status Update on CIOMS XII

Leo Plouffe, MD

Head of Global Patient Safety
Gilead Sciences, United States

Leo is a native of Montreal, Canada. He completed his medical studies and a residency in Obstetrics and Gynecology at McGill University, followed by a fellowship in Reproductive Endocrinology and Genetics and serving as a faculty member at the Medical College of Georgia. This was followed by a number of roles with increasing responsibility in development, medical affairs at pharmacovigilance at Eli Lilly, Bayer Pharmaceuticals and Gilead Sciences, Inc. He currently is Vice President and Global Head of Patient Safety at Gilead. He is a member and sub-group co-chair of the Council for International Organizations of Medical Sciences (CIOMS) workgroup XII, on Benefit-Risk Assessment of Medicinal Products.

Structured Benefit-Risk Assessment in AstraZeneca

Jiyoon Park, PhD

Safety Data Scientist, Global Patient Safety
AstraZeneca, United States

Her work focuses on structured benefit-risk (sBR) assessment, leveraging her Ph.D. in Quantitative Research Methodology to drive patient-centric approaches in drug development. She specializes in quantifying uncertainty in benefit-risk trade-offs using methodologies like Bayesian analysis and Multi-Criteria Decision Analysis (MCDA). Jiyoon has contributed to key safety analytics and patient-centered frameworks aligned with regulatory requirements. Her work informs decision-making through innovative tools, automation, and collaboration with cross-functional teams, ensuring optimized therapeutic outcomes and patient safety.

Patient Focused Structured Benefit-Risk Assessment: Visualization and Patient-Focused Approaches

Ellen M Janssen, PhD

Director, Global Epidemiology, Benefit-Risk Assessment
Janssen Research & Development LLC, United States

Ellen Janssen in a Director of Benefit-Risk Assessment/Epidemiology at Johnson and Johnson. In her work she lead structured benefit-risk assessments throughout the product lifecycle and conducts patient preferences studies to inform patient-focused decision making. Ellen is passionate about ensuring that patient-focused decision making is incorporated throughout the medical product lifecycle. She is/has been involved as a preference expert in IMI PREFER, MDIC, BIO Patient Focused Drug Development Task Force, and the ISPOR Taskforce on using patient preferences to inform decision making.

Day 3 Jan 29, 2025

7:30 AM — 12:45 PM — East Foyer – 2nd Floor

Conference Registration

7:30 AM — 8:00 AM — Key Ballroom 1-6

Networking Breakfast

8:00 AM — 9:15 AM — Key Ballroom 7-12

Session 11: Navigating Pharmacovigilance in Small Pharma: Strategies for Building Sustainable Frameworks

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
- Discuss how to design a plan to establish the PV function at a small pharma
- Recognize what is needed to demonstrate adequate oversight of PV vendors

Track: General Session

Session Chair(s)

Bethany Van Veen

Pharmacovigilance Consultant
Perspective Pharmacovigilance, United States

Bethany Van Veen has focused her entire career on pharmacovigilance (PV). In 2017, she founded Perspective Pharmacovigilance, a think tank of PV experts. PPV's global staff of industry leaders, former PV department heads, and ex-regulators, design innovative solutions to a rapidly changing PV landscape. Bethany is passionate about cultivating PPV's unique environment where the global team can do the work they love with people they trust. Bethany is also an adjunct professor at San Francisco State University teaching the Safety Monitoring Course for the Clinical Trials Design and Management Certification.

Speaker(s)

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

James Cross, PhD, MS

Founder
Cross BioConsulting, United States

Jamie is the founder and principal consultant of Cross BioConsulting LLC, providing regulatory services. With a career spanning nearly 25 years, he served most recently as Senior Vice-President of Regulatory Affairs at Asher Biotherapeutics, where he built the Regulatory, Quality, Safety, and Medical Writing functions from the ground up, culminating in the approval of two INDs, thereby transforming the company from a research-stage to a clinical-stage organization. He has held roles of increasing responsibility at large and small companies, including Genentech, Halozyme, Forty Seven. He started his career at the US Food and Drug Administration, Office of New Drugs, supporting drug review activities and policy development.

Speaker

CJ Delgra, MD

PV Physician Medical Advisor
Perspective Pharmacovigilance, United States

Over the past 25+ years, CJ Delgra, developed significant expertise in medical safety review, case management and operations, aggregate safety reports, inspection management, vendor oversight and outsourcing, process development, during his time within PV departments at several global companies. Currently a Strategic PV Advisor with Perspective Pharmacovigilance. Previously, CJ was the VP Medical Review & Case Management, at BeiGene (now BeOne) and has worked in leadership positions at Amgen, Genentech/Roche, Merck-MSD, and Celgene/BMS. CJ has been active with Transcelerate PV projects, and a past speaker at ASCO and LUNGevity on compliance with the FDA “Final Rule” and reducing uninformative IND Safety reports to FDA and Investigators.

Navigating PV in Late-Stage Development in Small Biotech

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.

Transitioning to Post-Approval in Small Biotech

Stephen Knowles, MD, MRCP

Vice President of Drug Safety Pharmacovigilance
Crinetics Pharmaceuticals, United States

Dr. Steve Knowles has 20+ years of experience in the pharmaceutical industry. Currently he is VP Drug Safety & Pharmacovigilance at Crinetics Pharmaceuticals, a clinical stage Biotech company. Prior to this he was Chief Medical Officer and head of pharmacovigilance at Halozyme Therapeutics and prior to that worked at Eli Lilly in various roles of increasing responsibility in Global Patient Safety. Steve earned his medical degree in the UK and worked in the UK Health Service for 17 years.

9:20 AM — 10:35 AM

Key Ballroom 7-12

Session 12: Mastering FDA's New Draft Guidance: Optimizing Data Monitoring Committees in Clinical Trials

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 :

- Interpret 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
- Illustrate how a DMC can effectively assist safety organizations in evaluation of potential safety signals in ongoing clinical trials

Track: General Session

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 20 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 aggregate safety assessment plans, internal data monitoring committees, and IND aggregate safety reporting procedures. In addition, she co-leads Workstream One of the American Statistical Association's Biopharma Safety Working Group.

Speaker(s)

Data Monitoring Committees in Clinical Trials: Realities and Myths

Frank W. Rockhold, PhD, MSc

Professor of Biostatistics
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.

Considerations for Enhancing the DMC Package for End-to-End Exploration and Analysis by Leveraging Visual Analytics

Melvin Slaighter Munsaka, PhD, MEd, MS

Senior Director, Head Safety Statistics
AbbVie, United States

Melvin S. Munsaka is a Senior Director and Head of the Safety Statistics at AbbVie in the Statistical Sciences and Analytics Department. He has a PhD in Mathematical Statistics from Queen's University in Canada. He has been in the industry for more than 25 years. He co-leads the DIA Bayesian Scientific Working Group Safety Subteam and the ASA BIOP Section Safety Scientific Working Group Methodology Sub-team, and some initiatives of the PHUSE Safety Analytics and the Data Visualization and Open-Source Technology Working Groups. He is the Publicity Chair of MBSW and an Editorial Board Member of Contemporary Clinical Trials and a lecturer at the University of Chicago Graham School.

10:35 AM — 11:15 AM Key Ballroom 1-6

Networking Break in the Exhibit Hall

10:40 AM — 11:10 AM East Foyer – 2nd Floor

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

Post-market safety studies are critical for understanding the real-world impact of drugs and devices, particularly for underrepresented populations such as pregnant women. This presentation will highlight how real-time electronic health record (EHR) data, enriched with clinical notes and images, enables robust post-market safety research. Research examples will showcase how deterministic mother-child matching for more than 1.1 mother-child pairs can fill critical gaps in pregnancy safety research.

Learning Objective :

- Using real-time EHR data to enhance post-approval safety studies for drugs and devices
- Insights into maternal, obstetric, and neonatal/infant outcomes sourced from mother-child EHR pairs
- Applications of clinical notes and imaging to expand the scope and depth of pregnancy safety research

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Transforming Post-approval Research with Real-time EHR Data: Spotlight on Pregnancy Studies

Conor Wyand

Senior Director, Partner Solutions
Truveta, United States

Conor Wyand currently is the Senior Director of Research Solutions at Truveta where he leads a team responsible for engaging with potential new life science customers. Prior to joining Truveta in 2021, Conor spent six years in various leadership positions at Optum Life Sciences, working with pharmaceutical and medical device manufacturers across the value chain to generate real-world evidence for therapeutics and devices. Conor graduated from Brown University with a bachelor's degree in applied mathematics and economics.

11:15 AM — 12:30 PM

Key Ballroom 7-12

Session 13: Innovations in Safety Signal Detection and Causality Assessment: From Knowledge Graphs to Best Practices

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
- Recognize the PhUSE recommendations for the use of AE term groupings in signal detection
- Discuss the various approaches to considering evidence in support of a causal relationship between the drug and an adverse event

Track: General Session

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)

PHUSE White Paper: Use of Adverse Event Groupings in Clinical Trial Safety Assessments

Peg Fletcher, MD, PhD

President
MedAssessment, Inc., United States

An oncologist and clinical pharmacologist with over 25 years' experience in drug development and safety of oncology, neurology, and metabolic disease products, Peg developed TAP Pharma's safety review process, led the protocol review team, and has led or supported safety portions of many NDAs and sNDAs. For the past 12 years she has led MedAssessment, a small PVG CRO focused on safety in early development. Peg received her MD & PhD (biochemistry) from U Chicago and boards in Oncology and Clinical Pharmacology.

Mutlimodal Safety Data products to enhance Signal Management and Detection

Balmeet Gurm, MD

Executive Director, Therapeutic Area Lead, patient safety
Bristol Myers Squibb, United States

Balmeet Gurm is an accomplished physician with extensive experience in the pharmaceutical industry, specializing in oncology and cardiovascular therapeutic areas. Currently serving as Executive Director, Therapeutic Area Lead in Patient Safety at Bristol Myers Squibb (BMS), Balmeet brings a wealth of expertise in pharmacovigilance, risk management, and drug development. Balmeet transitioned to the pharmaceutical industry after practicing medicine for a few years and has held critical leadership roles in safety and pharmacovigilance across multiple organizations. Throughout a distinguished career, Balmeet has contributed significantly to advancing patient safety, regulatory compliance, and the successful development of innovative therapie

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

Salman Afsar, MD, MHA

Senior Director and Signal Management Team Chair
Bristol-Myers Squibb Company, United States

Dr. Salman Afsar, Senior Director and Signal Management Team Chair at Bristol Myer Squibb, is a distinguished physician specializing in Medical Safety Assessment. With a strong background in the pharmaceutical industry including notable positions at Sanofi and Astellas, Dr. Afsar brings extensive expertise to his role. Before transitioning to industry he made significant contributions in academia and clinical practice, earning him prestigious awards for his exceptional work.

12:30 PM — 12:45 PM

Key Ballroom 7-12

Closing Remarks

Speaker(s)

Sorcha McCrohan, MS

Scientific Project 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 Patient 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