Virtual

Jan 26, 2026 7:30 AM - Jan 28, 2026 12:45 PM

(US Eastern Standard Time)

Global Pharmacovigilance and Risk Management Strategies Conference

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Print Agenda

Day 1 Jan 25, 2026

8:30 AM — 12:00 PM

Short Course: Introduction to Benefit–Risk Management: Building Strong Assessments for Smarter Decisions

Session Chair(s)

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.

Jillian Horvath, MPH

Associate Director, Global Risk Management
Jazz Pharmaceuticals, United States

Jillian has over 20 years of experience in the pharmaceutical/biotech industry and is currently Associate Director, Global Risk Management at Jazz Pharmaceuticals. Prior to her current role, she held various positions across R&D in preclinical safety assessment, regulatory affairs, project management, benefit-risk evaluation, clinical safety/pharmacovigilance, and risk management. She is currently supporting the American Statistical Association Biopharmaceutical Section Safety Scientific Working Group (Workstream 1) Benefit Risk Assessment Planning (BRAP) Taskforce.

1:00 PM — 4:30 PM

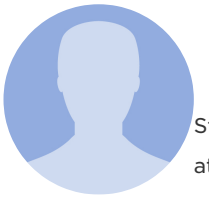
Short Course: Translating Global Risk Management Guidance Into Innovation and Patient Safety

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.



Representative Invited

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.

Gita Toyserkani, PharmD, MBA

Regulatory Strategy Lead
Perspective Pharmacovigilance, United States

Dr. Gita Toyserkani is Regulatory Strategy Lead at Perspective Pharmacovigilance, where she advises life sciences companies on regulatory strategy across drug safety, risk management, and benefit–risk assessment. She brings more than 20 years of experience at the U.S. Food and Drug Administration, most recently as Associate Director in the Office of Medication Error Prevention and Risk Management. At FDA, she led the development of the REMS Logic Model, advanced REMS design and evaluation, and helped shape modern approaches to risk minimization. Gita has authored 20+ peer-reviewed publications and is an invited speaker on regulatory science and risk management. She is also the Founder of DelMetrik, advancing regulatory science into practice

Day 2 Jan 26, 2026

9:30 AM — 10:00 AM

Hosted Session/Non-CE Case Study hosted by APCER Life Sciences: From Acquisition Support to Strategic Partnership: A Case Study of Global Pharmacovigilance and Risk Management System Setup

Hosted Session/Non-CE Hosted by APCER Life Sciences: From Acquisition Support to Strategic Partnership: A Case Study of Global Pharmacovigilance and Risk Management System Setup
Track: Hosted Session

Session Chair(s)

Vineet Kacker, PhD

Managing Director & Global Technical Head
APCER Life Sciences, 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.

10:00 AM — 11:30 AM

Welcome and Session 2: Navigating FDA, EMA, and MHRA Regulatory Policy Shifts Updates to Stay Ahead of Compliance

This session will provide updates from the Office of Surveillance and Epidemiology (OSE) within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA) on the Office's recent advances/initiatives in pharmacovigilance and risk management strategies. The session will also provide an overview of the strategic direction of the MHRA with a focus on developments in signal and benefit/risk assessment.
Learning Objective : At the conclusion of this session, participants should be able to:

- Describe recent FDA updates regarding pharmacovigilance and risk management strategies and assessing safety signals
- Explain the MHRA approach to assessment of signals and benefit risk evaluation and describe recent updates and strategic developments

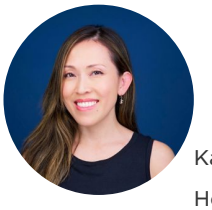
Track: General Session

Session Chair(s)

Sorcha McCrohan, MS

Sr. Scientific Project Manager
DIA, United States

Sorcha McCrohan is a Senior Scientific Project Manager for Global Science 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 franchise. Sorcha holds a BA in Sociology from Mount Holyoke College and an MSc in Global Health, Disease Prevention & Control from Georgetown University.



Katie Truong

SVP & Managing Director, DIA Americas and Global Head of Business Operations
DIA, United States

Katie Truong is the Senior Vice President & Managing Director of DIA Americas and the Global Head of Business Operations. In her role, Katie focuses on driving growth, optimizing operations, and enhancing business performance. With experience spanning various industries, including government, design, and professional services, she brings a wealth of knowledge to DIA. Katie holds a Bachelor of Arts degree with High Distinction from the University of Virginia and an MBA from New York University Stern School of Business, specializing in strategy, leadership, and change management.

Scott Janiczak, PharmD, MPH

Team Leader, Division of Pharmacovigilance-I, OSE, CDER
FDA, United States

LCDR Scott Janiczak, PharmD, MPH, BCPS, is a pharmacy officer in the U.S. Public Health Service, who serves as a Team Leader in the Division of Pharmacovigilance-I (DPV-I) within FDA's Center for Drug Evaluation and Research. In this role, he leads a multidisciplinary team reviewing post-market drug safety across therapeutic areas. Previously, he served as a safety evaluator in DPV-I (2020-2024) and regulatory affairs pharmacist in FDA's Office of Generic Drugs (2014-2020). LCDR Janiczak earned his PharmD from Midwestern University, completed a PGY-1 residency at Franciscan Health (Dyer, IN), and is board certified in Pharmacotherapy. He frequently presents on FDA drug safety initiatives at national conferences and academic institutions.

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)

Updates from the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research

Gerald Dal Pan, MD, MHS

Director, Office of Surveillance and Epidemiology, CDER
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.

Speaker

Georgy Genov, MD

Head of Pharmacovigilance Office
European Medicines Agency, Netherlands

Dr Georgy Genov is the Head of Pharmacovigilance Office, within Quality and Safety of Medicines Department, European Medicines Agency (EMA). The office oversees and manages lifecycle pharmacovigilance activities in the EU, including signal detection and management; evaluates the impact of regulatory interventions and develops pharmacovigilance guidelines and standards; ensures leadership, coordination and clear roles and responsibilities for a quality assured EMA's and EU pharmacovigilance systems; collaborates closely with EMA

scientific committees and working parties, in particular the Pharmacovigilance Risk Assessment Committee (PRAC). Oversees the development and maintenance of IT systems for pharmacovigilance.

Updates on Key Regulatory Strategies from the MHRA

Jenn Matthissen, MSc

Head of Gastrointestinal system, Nutrition, Endocrine and Fertility
MHRA, United Kingdom

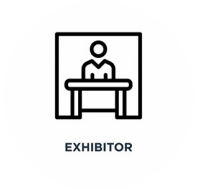
Jenn Matthissen is Head of Gastrointestinal System, Nutrition, Endocrine and Fertility at the MHRA, where she leads a multi-disciplinary team overseeing safety surveillance and benefit–risk activities across complex therapeutic areas. She brings over a decade of experience in pharmacovigilance across a range of therapeutic areas in both medicines and medical devices, and strategic benefit-risk regulatory decision-making. Jenn is a strong advocate for embedding patient voice and lived experience into regulatory processes to drive more transparent and effective outcomes for patients.

11:30 AM — 12:30 PM

Meal Break – Visit the Virtual Exhibits!

View Exhibitors

Session Chair(s)



Sponsored Sessions

United States

12:30 PM — 1:45 PM

Session 3: Adapting Risk Minimization Strategies Across the Product Lifecycle

Journey of Risk Mitigation from decision-making for core risk management strategies, to lifecycle management and modifications as safety profiles evolve and effectiveness is evaluation, through programmatic elimination.

- Refresher on risk minimization strategy decision-making and approach
- Modification of risk minimization measures/REMS post study read-out utilizing updates for a CV drug: reduction in ECHO monitoring, learnings, implementation, and regulatory success

Removal/Elimination of aRMMs and REMS: use case for an anticoagulant product, and CAR-T therapies regulatory success, and approach to analysis

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

- Describe best practices for setting core risk minimization approach
- Identify approaches for modification to risk minimization programs when new data is available
- Define various approaches and rationales for eliminating additional risk minimization measures and REMS programs

Track: General Session

Session Chair(s)

Balmeet Gurm, MD

Executive Director, Therapeutic Area Lead Cardiovascular and EBs, 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

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.

Speaker(s)

Risk Management Evolution: The Eliquis ARMM Decommissioning Story

Kinjal Patel, PharmD

Patient Safety Scientist
Bristol Myers Squibb, United States

CAMZYOS REMS Data Support of Label Update

Dewey Seto

Director, REMS Strategy
Bristol Myers Squibb, United States

Removal of CAR T REMS

Liza Rodriguez, DrSc, MPH

AD, REMS Strategy & Submissions, Patient Safety, Safety Evidence & Sciences
Bristol Myers Squibb, United States

Liza Rodriguez is Associate Director of Global Risk Management at Bristol Myers Squibb, leading US REMS Strategy and Submission programs. She drives REMS development, lifecycle management, and decommissioning—including recent CAR T REMS removals—and partners across Regulatory, Safety, Medical, IT, and external stakeholders. Liza also leads the Education & Certification Working Group within the REMS Industry Consortium and presents regularly at global safety forums.

1:50 PM — 2:20 PM

Hosted Session/Non-CE: Case Study hosted by ArisGlobal: Signals Management Reimagined: Harnessing Data Science for Smarter Risk Management

Hosted Session/Non-CE Hosted by ArisGlobal: Signals Management Reimagined: Harnessing Data Science for Smarter Risk Management
Track: Hosted Session

Session Chair(s)

Paramdeep Singh

Associate Vice President
Product Management, ArisGlobal, India

2:30 PM — 3:45 PM

Session 4: Turning Guidance into Action -- Practical Pathways for Effective Risk Management

The session will review the impact of recent guidance from FDA and EMA on the practical steps that should be taken when developing an understanding of contextual product risks, defining risk management objectives and then designing, testing and implementing risk management tools. The emphasis of the session will be on practical approaches to align user-tested RM tools to their measures of effectiveness. The session will explore the options and approaches that are available to obtain effectiveness data from traditional cross sectional surveys to real-time, real-world data capture.

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

- Define the steps that should be taken to assess product risks in the context of their use within the healthcare system
- Employ a logical approach and framework to define risk management objectives, tools and their measurement
- Describe the key characteristics of different risk management implementation approaches

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.

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)

The FDA's REMS Logic Model: A Framework Linking Design, Implementation, and Evaluation

Gita Toyserkani, PharmD, MBA

Regulatory Strategy Lead
Perspective Pharmacovigilance, United States

Dr. Gita Toyserkani is Regulatory Strategy Lead at Perspective Pharmacovigilance, where she advises life sciences companies on regulatory strategy across drug safety, risk management, and benefit–risk assessment. She brings more than 20 years of experience at the U.S. Food and Drug Administration, most recently as Associate Director in the Office of Medication Error Prevention and Risk Management. At FDA, she led the development of the REMS Logic Model, advanced REMS design and evaluation, and helped shape modern approaches to risk minimization. Gita has authored 20+ peer-reviewed publications and is an invited speaker on regulatory science and risk management. She is also the Founder of DelMetrik, advancing regulatory science into practice

Practical Applications of GVP XVI: An Overview of the Outputs of the Recent DIA RM Information Day

Priya Bahri, PhD, RPh

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

Priya Bahri, RPh, PostGradDipEpi, PhD, FISoP, at EMA since 1996, is now EMA's Lead Pharmacovigilance and Risk Management Guidance and Policy. In this role, she oversees the developement of the EU Good Pharmacovigilance Practices (EU-GVP) and also instigates frameworks, research and engagement 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 at Utrecht University. She is the editor of the Springer textbook "Communicating about Risks and Safe Use of Medicines - Real Life and Applied Research".

3:50 PM — 5:05 PM

Session 5: Fit-for-Purpose Pharmacovigilance: Real-World Best Practices and Strategic PV Planning for Small and Emerging Companies

Small and mid-size biopharma companies face unique pharmacovigilance challenges—balancing lean resourcing with complex regulatory expectations. This session highlights the importance of embedding strategic safety planning and benefit–risk thinking early in clinical development, ensuring PV is seen as a value driver rather than a cost center. Panelists will explore how early company oversight of vendors and strong operational foundations help prevent compliance gaps, while systematic safety planning leads to better outcomes. Through real-world case studies, panelists will illustrate the downstream consequences of insufficient PV planning and share examples of how proactive frameworks can prevent such outcomes. Attendees will leave with actionable tools to build scalable safety infrastructure, strengthen cross-functional credibility, and position PV as a driver of long-term program success.
Learning Objective :

- Demonstrate strategies to position PV as a value driver
- Discuss benefits of early, systematic safety planning
- Analyze real-world case studies where inadequate PV planning caused regulatory delays, restrictive labels, or significant inspection findings
- Implement a “first 100 days” framework for new PV leaders
- Outline approaches for cross-functional alignment to elevate PV’s influence and recognition within the organization

Track: General Session

Session Chair(s)

Barbara Hendrickson, DrMed, MD

Clinical Associate, Pediatric Infectious Diseases
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.

Bethany Van Veen

CEO and Founder
Perspective Pharmacovigilance, United States

Bethany Van Veen has focused her entire career on pharmacovigilance (PV). Starting in the late 1990s, she began her PV career in drug safety operations at Elan Pharmaceuticals and continued to hold a variety of operational leadership roles within small and large organizations including J&J, Millennium and InterMune. She began her consulting career in 2013 and has advised over 125 companies. She values the importance of leveraging strong PV foundational skills to curate new ways of meeting global challenges. 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.

Speaker(s)

Speaker

Renee Breed

Pharmacovigilance
Independent Consultant, United States

Renee Breed is an Independent Pharmacovigilance Consultant located in San Francisco, California with more than 23 years of experience in case management, global safety reporting, safety science, quality management, and safety systems. Prior to starting her consulting business in January 2025, Renee was most recently Vice President, Medical Safety Operations (Vincerx Pharma) and previously held positions as Head of Medical Safety Operations and Excellence (Acerta Pharma/AstraZeneca), Head of Drug Safety Operations (Onyx/Amgen), Head of Pharmacovigilance (Sunesis), and Head of Drug Safety Risk Management Operations (InterMune/Roche). Renee holds a BS in Biology from the University of Wisconsin at Madison.

Speaker

Famina Hemani, PharmD

Vice President, Head of Pharmacovigilance
Tourmaline Bio, United States

Speaker

Sarah Chesler, BSN

Vice President, Pharmacovigilance
Beam Therapeutics Inc., United States

Sarah Chesler has more than 20 years of experience in drug development, spanning both small and large organizations. While she has contributed across multiple functions within clinical development, most of her career has been dedicated to establishing and scaling pharmacovigilance capabilities in small and emerging biotech

companies. She has a special interest in advancing therapies in rare diseases and cell and gene therapy. Sarah is currently the Vice President of Pharmacovigilance at Beam Therapeutics.

Day 3 Jan 27, 2026

7:55 AM — 8:25 AM

Hosted Session/Non-CE: Case Study hosted by COD Research USA INC: Decode the Risk Management for the Combination Products: The Operational Challenges and Actionable Safety Strategies

Advancements in personalised medicines are with newer delivery systems. This poses unique challenge for risk management, since medicines have devices combined as whole product. Lack of regulatory guidance, use of digital components, device's inherent risk, efficacy and safety of drug's dependency on device and user errors are some of the challenges making it complex. Integrated principals on safety strategies along with agile multidisciplinary team are utilized to decode on such challenges. The session would flow with historical and current examples/own case study to unravel the balancing act between drug & device.
Learning Objective :
Featured Learning Points:

- The challenges in developing Risk Management strategies for Combination product
- What are the principles and model utilized while creating such strategies, how it operationally performed
- Historical and current case studies and solutions with the Best Practices and Future Outlook

Track: Hosted Session

Session Chair(s)

Jay Dave, DDS, MSc
Technical Director-Patient Safety, Risk Management & RA
COD Research Pvt LTD, India

8:30 AM — 9:45 AM

Session 6: Let’s Go Global: Regional Regulatory Updates from Africa and the Middle East

There has been profound evolution of pharmacovigilance and risk management related regulation and regulator status across Africa and the Middle East over the last decade. Please join a group of regulators, and other supporters of regulatory expansion and harmonization in this region for a description of the progress and updates in this region that are relevant to all attendees.
Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize pertinent regulatory organizational updates in the last 5-10 years in Africa and the Middle East
- Describe the efforts for development of, and pertinent new regulatory structures in the region
- Identify key new regulatory expectations and requirements from the Africa/Middle East region

Track: General Session

Session Chair(s)

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.

Speaker(s)

Speaker

Delese Mimi Darko, PhD, MBA, RPh, RAC

Director General
African Medicines Agency (AMA) , Rwanda

Dr. Mimi Darko graduated as a pharmacist with an MBA. Her career in food and health products regulation spans over 30 years. Prior to her appointment as AMA's first DG, she rose through the ranks of the FDA to become its first female CEO in 2017. She led FDA’s designation as a Regional Center of Regulatory Excellence in Medicines Safety, Clinical Trials and Drug Registration. She contributed to the growth of research and of the local manufacturing industries in Ghana Mimi Chairs the Steering Committee of WHO African Vaccines Regulatory Forum and serves on several international and local expert committees. She has received several awards for her exemplary work. She is a devout Christian and married with two children.

Speaker

Deirdre McCarthy, MSc

Pharmacovigilance Lead, Regulatory System Strengthening
Gates Foundation, United States

Deirdre is a Senior Program Officer and Pharmacovigilance Lead at the Gates Foundation, overseeing grants that support the African Union's first continental safety surveillance platform for the African Medicines Agency. With over 20 years of PV experience across regulatory, industry, and non-profit sectors in the EU, US, and Latin America, she brings a global perspective to post-marketing safety, compliance, and global health. She has lectured at Tufts University and is a Fellow of the International Society of Pharmacovigilance (ISoP).

Speaker

Fadi A Alanazi, MPH, RPh

Senior Expert - Pharmaceuticals Safety
Saudi Food and Drug Authority, Saudi Arabia

Fadi is a Senior Expert in Pharmacovigilance and Drug Safety with over 15 years of experience across regulatory authorities, healthcare institutions, and the pharmaceutical sector in Saudi Arabia. He currently serves at the Saudi Food and Drug Authority (SFDA), leading national risk minimization initiatives and digital pharmacovigilance integration projects. He is also a Board Member of the Saudi Arabian Anti-Doping Committee, contributing to regulatory governance and patient safety at a national level.

9:50 AM — 10:20 AM

Hosted Session/Non-CE: Case Study hosted by SeltaSquare: Reimagining Pharmacovigilance: Human-AI Interactive Intelligence

This case study highlights SELTASQUARE's use of AI to improve pharmacovigilance workflows through "iVigilance Square": "Case Processing", which automates ICSR data entry and XML generation, and "Safety Monitoring", which enhances literature monitoring and summarization. Together, they reduce manual workload and improve data quality while maintaining regulatory compliance. The presentation also introduces SELTASQUARE's internal AI tools for governance, prompt testing, and explainability—showing how AI supports both external PV processes and internal team efficiency.

Featured Topics

- Rethinking Pharmacovigilance: Challenges in Data Entry and Literature Review
- "iVigilance Square: Case Processing": Human-in-the-Loop ICSR Automation
- "iVigilance Square: Safety Monitoring": AI-Driven Literature Monitoring and Summarization
- Internal AI Tools for Governance and Explainability
- Building Trust: Human and AI Collaboration in Pharmacovigilance

Track: Hosted Session

Session Chair(s)

Sponsored Sessions

United States

EXHIBITOR

Speaker(s)

Kyunghee Han

PV & PVQMS Director
SELTA SQUARE Inc., Korea, Republic of

Minkyung Shin

CEO
SELTA SQUARE Inc., Korea, Republic of

10:30 AM — 11:45 AM

Session 7: Driving Understanding of Human Risk Through Nonclinical Studies in Early Clinical Trials

The session starts with an overview of standard preclinical assessments. This overview will include species selection, general GLP toxicology, safety pharmacology, dose determination for oncology and non-oncology drugs, as well as specialized studies like immunotoxicity and phototoxicity. The evolving FDA perspective on New Approach Methodologies (NAMs) and reducing animal testing in preclinical safety studies also will be discussed. Interactive case studies with audience engagement and interdisciplinary panel discussion are planned. The panel discussion will address differences in approaches for biologics versus non-biologics, limitations of transgenic animal models, the translatability of animal findings to humans and the potential impact to early human studies with a move away from animal studies to NAMs.
Learning Objective : At the conclusion of this session, participants should be able to:

- Explain the current approach to assembling a nonclinical safety package to support early human clinical studies
- Describe FDA's recently posted Roadmap to reducing animal testing and types of new approach methodologies
- Appraise how nonclinical data impacts the safety planning of early human clinical trials

Track: General Session

Session Chair(s)

Barbara Hendrickson, DrMed, MD

Clinical Associate, Pediatric Infectious Diseases
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.

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. 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)

Overview of Current Approach to the Preclinical Safety Package

Sherry Ralston, PhD

Head of Development Biological Sciences Portfolio Leadership Group
AbbVie, United States

Sherry Ralston is currently Head of the Development Biological Sciences Portfolio Group at AbbVie, where she leads a group responsible for the strategic oversight and the execution of the non-clinical activities to support the pipeline. Sherry has 25+ years of experience in the pharma industry in toxicology. Through the years, she has had many interactions with regulatory groups, involved in many drug submissions (i.e. IND, CTA and/or NDA/MAA), and is externally active in various consortiums as an AbbVie representative, including current Chair of IQ DruSafe Consortium. Sherry received her BS at Allegheny College and her PhD at Purdue University.

FDA Roadmap to Reducing Animal Testing and New Approach Methodologies

Nakissa Sadrieh, PhD

Senior Advisor for New Approach Methodologies, CDER
FDA, United States

Nakissa joined the FDA in 1996 as a pharmacology and toxicology reviewer. In 2002 she joined CDER OPQ as the Associate Director for Research Policy and Implementation. During that role, Nakissa worked on numerous projects focusing on research and policy development in drug quality, drug safety, bioequivalence of generic drugs,

biopharmaceutics, nanotechnology, computational toxicology and environmental assessment. In 2021, she returned to CDER OND as the Senior Advisor for New Approach Methodologies, where she currently focuses on developing a path towards the regulatory acceptance of complex in vitro methods to support drug safety and meeting the 3Rs.

Case Studies Examining the Role of Nonclinical Data in Human Safety Risk Assessment

William E. Achanzar, PhD

Scientific Executive Director, Nonclinical Safety
Bristol Myers Squibb, United States

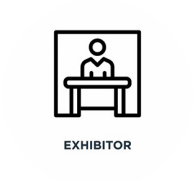
Dr. Achanzar is currently the Nonclinical Safety Therapeutic Area Head for the Cardiovascular and Neuroscience at Bristol-Myers Squibb, where he oversees the nonclinical safety strategy for all assets in these disease areas. He received his PhD in Molecular and Cellular Biology from the University of Arizona. After graduating, he trained in toxicology as a postdoctoral fellow at the National Cancer Institute with Dr Michael Waalkes. He joined BMS in 2003 as a junior toxicologist and, over the past 22 years, has acted as the toxicology lead for a number of early- and late-stage drug development programs across multiple disease areas and modalities, including oligonucleotides.

11:45 AM — 1:00 PM

Meal Break – Visit the Virtual Exhibits!

View Exhibitors

Session Chair(s)



Sponsored Sessions

United States

1:00 PM — 2:15 PM

Session 8: What's New in Advancing Signal Detection? Smarter Tools for Safety Evaluation

This session will provide an update on tools that aid in evaluating causality assessments of drug-induced liver injury (DILI). Some signal detection tools and methods employ various statistical methods, but this session will offer caution with some of these approaches instead highlighting the appropriate application of statistical methods in signal detection.

Finally, while the Sentinel program has been a powerful tool for FDA to perform safety risk evaluations, it is not available to the pharmaceutical industry. However, a “subset” of Sentinel, known as IMEDS, is a program for safety evaluations that can be utilized by pharmaceutical companies. Experts in each of these areas will share the latest thinking on these topics.
Learning Objective : At the conclusion of this session, participants should be able to:

- Describe how the RECAM method improves upon the RUCAM method for DILI assessments
- Appreciate the appropriate use and limitations of statistics in signal detection and evaluation
- Discuss how sponsors can use the IMEDS tools to evaluate safety signals using Sentinel-level data resources

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)

Updates on DILI Causality Assessment

Javier Waksman, MD

President
PharmaSec LLC , United States

Dr. Waksman is the president of Pharmasec, a drug safety consulting company. He is also the Head of Drug Safety at Centessa Therapeutics. He has 15 years of experience in drug safety/pharmacovigilance, holding various leadership roles, including leading drug safety teams. Dr. Waksman specializes in Internal Medicine and Medical Toxicology, with expertise in hepatotoxicology and Drug-Induced Liver Injury. He is also a Fellow of the American Academy of Clinical Toxicology. Before joining the industry, Dr. Waksman was the director of the Medical Toxicology Practice at the University of Colorado and is currently on the clinical faculty of UCSF. He was a member of the CIOMS DILI work group and hepatic committees.

Key Considerations to Avoid Misuse of Statistics in Safety Signal Detection and Evaluation

Ed Whalen, PhD

Senior Director, Biostatistics
Pfizer Inc, United States

Ed Whalen has worked in the industry for 35 years and partially focused on safety related questions both at the project level and in general for the last 20 years. His background has covered drug development primarily in CNS and pain with some prior experience in anti-infectives, oncology and cardiovascular.

How the Innovation in Medical Evidence and Development Surveillance (IMEDS) Program Leverages Sentinel Capabilities for Safety Evaluations

Carla Rodriguez-Watson, PhD, MPH

Director of Research
Reagan-Udall Foundation for the FDA, United States

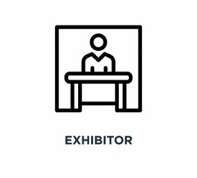
Dr. Rodriguez-Watson is focused on continuously developing and enhancing a portfolio of work that leverages real-world data and experiences to inform and conduct clinical and post-market drug safety and effectiveness studies to improve population health. Key projects bring together communities of experts to develop and advance frameworks and tools to systematically describe and improve data sources and methods for use in pre- and post-market studies of product safety and effectiveness. Such efforts serve to operationalize regulatory guidance and support practical interpretation in a collaborative environment. Dr. Rodriguez-Watson brings her extensive background in public health, epidemiology, and health outcomes research to this work.

2:20 PM — 2:50 PM

Hosted Session/Non-CE: Case Study hosted by RxLogix: One System, One Truth: Transforming Safety Surveillance Through End-to-End Integration

Track: Hosted Session

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

Instructor

Suranjan De

Vice President Client Relations & Product Innovation
RxLogix, United States

3:00 PM — 4:15 PM

Session 9: Harnessing AI and Emerging Tech to Transform Pharmacovigilance

Session Description: This session covers the cutting-edge applications of digital twins in patient safety, especially where real-world data is limited or hard to obtain, such as in ethical constraints, small patient populations, or complex scenarios. It highlights work from major international collaborations like the EU Human Digital Twin (EDITH) and Virtual Human Initiative, enabling the audience to understand current uses and emerging opportunities for digital twins. Additionally, it showcases practical AI/ML tools in pharmacovigilance and risk management (PVRM), including predictive safety modeling, automated data extraction, safety hypothesis generation, and evidence triage. The session also addresses the use of real-world evidence (RWE) in regulatory submissions and post-authorization safety studies (PASS).
Learning Objective :

- The audience will gain an overview of current and future uses of digital twins in patient safety and how the methodology is driven forward by international consortia
- Participants will learn how AI/ML methods can enhance early safety risk assessment in combination therapies and streamline safety data extraction using practical AI-driven workflows
- Participants will gain FDA perspective on use of real-world evidence in submissions and PASS

Track: General Session

Session Chair(s)

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. 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.

Balmeet Gurm, MD

Executive Director, Therapeutic Area Lead Cardiovascular and EBs, 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

Speaker(s)

Unlocking Combination Therapy Safety: Integrating Multi-Source Data with Generative AI

Kate Gofman, MD, PhD

Head of Predictive Safety
AbbVie, United States

Kate Gofman, MD, Ph.D., is currently working as a Global Patient Safety Physician at AstraZeneca. She has been with AstraZeneca for more than five years delivering global safety strategy and oversight for various compounds. Kate serves as an industry expert for automation & digital innovation. Before working with AZ, she practiced as a cardiologist and worked in various clinical leadership roles. Kate is a change agent and a blockchain enthusiast and has business education from Oxford and Stanford.

Speaker

Richard Forshee, PhD

Associate Director of Benefit Risk Assessment, OSE, CDER
FDA, United States

Richard Forshee is the Associate Director for Benefit-Risk Assessment in the FDA Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology. His portfolio includes benefit-risk assessment, real world evidence, pharmacoepidemiology, and artificial intelligence for regulatory science. He has won several awards including the FDA Award of Merit. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.

Speaker

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.

4:15 PM — 4:45 PM

Hosted Session/Non-CE: Case Study hosted by Veeva Systems: Connecting Data to Simplify and Accelerate Signal and Risk Management

Hosted Session/Non-CE Hosted by Veeva Systems: Connecting Data to Simplify and Accelerate Signal and Risk Management

Track: Hosted Session

Session Chair(s)

Tasim Begum

Senior Expert Advisor-Pharmacovigilance
Veeva Systems, United States

Diane Schierlitz

Senior Director Safety Strategy
Veeva, United States

Day 4 Jan 28, 2026

8:00 AM — 8:45 AM

Session 1: Fireside Chat with Dr. Robert Califf: Shaping the Future of Post-Market Safety, Global Harmonization, and More

Join Dr. Robert Califf for a candid, conversational keynote featuring personal reflections and forward-looking perspectives for pharmacovigilance and post market evaluation of medical products. The discussion will highlight challenges in post-market evaluation in the U.S., the importance of global harmonization in risk management, and the promising role of real-world data and real-world evidence in enhancing post-market safety. The conversation will also explore the evolving role of REMS in drug and biologic safety and its place in future benefit-risk management.

Track: General Session

Session Chair(s)

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Patient Safety Officer
Bristol Myers Squibb, 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)

Keynote Speaker

Robert M. Califf, MD

Instructor, Medicine
Duke University School of Medicine, United States

Dr. Robert Califf is an Adjunct Professor of Medicine at Duke University and a practicing cardiologist. He served as FDA Commissioner (2016–2017) and Deputy Commissioner for Medical Products and Tobacco. At Duke, he was Vice Chancellor for Clinical and Translational Research and founding director of the Duke Clinical Research Institute. A globally recognized expert in cardiovascular medicine and clinical research, he has over 1,200 peer-reviewed publications. Dr. Califf is a member of the National Academy of Medicine and has served on numerous FDA and NIH advisory boards. He co-founded the Clinical Trials Transformation Initiative and led several national research infrastructure programs.

8:45 AM — 10:00 AM

Session 10: DIAmond Session: The Safety Pulse: Executive Insights from Global Chief Safety Officers on Maintaining Best-in-Class PV Organizations

This fireside chat brings Chief Safety Officers/Heads of Safety from companies of varying sizes to explore the most pressing issues facing pharmacovigilance today. Topics include the future of PV, workforce development and organizational structure, empathetic leadership, the role of AI, and the impact of evolving global regulatory requirements. Attendees will gain firsthand insights into how top safety leaders are navigating change and shaping the future of drug safety.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify current key challenges and opportunities facing global PV organizations
- Contrast approaches for pharmacovigilance leadership best-practices in companies of various sizes
- Describe advice for developing and maintaining best-in-class pharmacovigilance organizations

Track: General Session

Session Chair(s)

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.

Speaker(s)

Speaker

Felix Arellano, MD, PhD, FISPE

Global Head Safety Risk Management
F Hoffmann-La Roche, Switzerland

A graduate in medicine from Universidad Autonóma de Madrid, Spain, postgraduate studies in pharmacoepidemiology at Macgill University, Montreal, Canada and in pharmaceutical medicine (combined Strasbourg, Basel and Freiburg universities) Dr Arellano has more than 20 years of experience in the safety and pharmacovigilance (PV) field in the pharmaceutical industry. A senior executive having worked in global roles for top 10 pharma in PV of medicines, consumer products, devices and vaccines Dr Arellano is Global Head of Safety Risk Management at F Hoffmann La Roche, Switzerland. With a career spanning all elements of PV Dr Arellano is committed to excellence in medical compliance and innovation in safety science to create value for society.

Speaker

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Patient Safety Officer
Bristol Myers Squibb, 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

Andrea Best, DO, MPH

Vice President and Head of Patient Safety
Gilead Sciences, United States

Andrea has 30 years of experience in academia and industry across a variety of roles (translational medicine, clinical development, medical affairs, quality and pharmacovigilance) and spanning numerous therapeutic areas including oncology, immunology/inflammation, virology, renal, neurology, anesthesia, general medicine and devices. She has led numerous discussions with global regulatory authorities on a variety of issues and has participated on several external collaborations related to regulatory system strengthening and pharmacovigilance including as a consultant to the Bill & Melinda Gates Foundation's regulatory system strengthening initiative in low to middle income developing countries.

Speaker

Jeremy Jokinen, PhD, MS

Vice President and Head Global Patient Safety
Argenx, United States

Jeremy Jokinen is the Vice President and Head, Global Patient Safety, argenx. Jeremy has led numerous cross-industry pharmacovigilance workgroups and initiatives for DIA, TransCelerate, and ICH, and is a frequent speaker at industry conferences. Jeremy has over 20 years of experience as a statistician in early phase to post-market pharmaceutical, biological, medical device, and patient safety research. He holds MS and PhD degrees in quantitative psychology from Ohio University

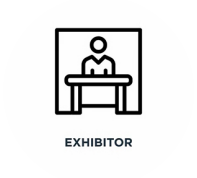
10:00 AM — 10:30 AM

Break – Visit the Virtual Exhibits!

View Exhibitors

Track: General Session

Session Chair(s)



Sponsored Sessions

United States

10:30 AM — 11:30 AM

Session 11: Even Big Data Can Feel Small: Addressing Safety Evidence Challenges with Practical RWE Solutions

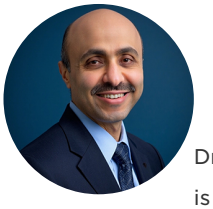
Real-world evidence is central to post-marketing safety evaluation, enabling assessment in broader populations, under routine care, and over long time. While studies involving rare outcomes or small populations may encounter feasibility and operational challenges, these hurdles also present opportunities for innovation and collaboration. These efforts can lead to more robust and adaptable study designs and improved regulatory engagement. This session features regulatory and industry experts sharing strategies with case examples on design adaptations, data sourcing, and regulatory engagement. Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize the importance of performing a feasibility assessment in RWD studies
- Apply structured frameworks to guide decision-making when encountering data limitations in post-marketing safety evaluations

- Discuss strategies for engaging with regulators proactively when feasibility concerns arise during study planning and execution

Track: General Session

Session Chair(s)



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

Vice President, Global Head of Medical Safety, Marketed Products and PDT, PSPV
Takeda Pharmaceuticals, 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)

Use of RWE to Support Safety Evaluations in the EU – DARWIN EU®

Andrej Segec, MPharm, MSc

Scientific Administrator
European Medicines Agency, Netherlands

Andrej Segec is a pharmacist by training (Comenius University, Bratislava, Slovakia) with an MSc in Epidemiology (London School of Hygiene and Tropical Medicine, London, UK). He has worked for the European Medicines Agency since 2008, in pharmacovigilance/signal management, monitoring of the EMA pharmacovigilance system, in surveillance and epidemiology, as committee manager for the operations of the Pharmacovigilance Risk Assessment Committee (PRAC) and as a risk management specialist for anti-infective therapies and vaccines during the COVID-19 pandemic.Currently, Andrej's focus is on the generation and use of RWE in regulatory decision making and the establishment and operation of the DARWIN EU® network.

Large Data for Drug Safety: Real-World, Real Challenges, Real Solutions

Simone P. Pinheiro, DrSc, MSc

Head, PharmacoEpidemiology Center of Excellence (PeCoE)
AbbVie, United States

Simone Pinheiro is Head of the Pharmaco-Epidemiology Center of Excellence at AbbVie, leading experts in regulatory pharmacoepidemiology, data science, and analytics to drive real-world evidence across the enterprise. With 15 years' experience—including leadership roles at FDA/CDER—and Doctorate and Master's degrees from Harvard, she is recognized for advancing RWE in regulatory decision-making and product development and shaping best practices in the field.

11:30 AM — 12:45 PM

Session 12: Hot Topics in PV -- Timely Insights Shaping the Future of Safety and Closing Remarks

Stay ahead of the curve with this interactive session designed to spotlight the most timely and relevant issues impacting global pharmacovigilance and risk management. Drawing on late-breaking developments, emerging regulatory priorities, and evolving industry practices, this session will feature thought-provoking discussions led by experts at the forefront of drug safety. Topics will be announced closer to the event to ensure the most current and impactful conversations for attendees.

Track: General Session

Session Chair(s)

Kal Elhoregy, RPh

Senior Director, Global Risk Management & Pharmacovigilance Compliance
Amneal Pharmaceuticals, United States

Kal Elhoregy is an accomplished healthcare industry executive with 25+ years' experience focused on implementation of Risk Minimization Programs, Quality Management Systems and Pharmacovigilance Quality and Compliance for companies within the pharmaceutical industry. As a strategist and accessible leader with experience in Pharmacovigilance and Quality Risk Management within the pharmaceutical industry, Kal has developed the infrastructure for managing all REMS programs and RMPs in collaboration with multiple disciplines. Kal believes in leadership and teamwork and focuses on what is important to achieve successful results in ensuring patient safety and regulatory compliance.

Mariette Boerstoel-Streefland, MD, MBA, MS

Senior Vice President, Patient Safety Officer
Bristol Myers Squibb, 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)

Speaker

Andrew Bate, PhD, MA

Vice President, Head of Safety Innovation and Analytics
GSK, 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 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.

Speaker

Elaine Lippmann, JD

Principal
Leavitt Partners, United States

Elaine Lippmann, J.D., is a Principal at Leavitt Partners based on Washington, D.C., bringing more than 15 years of leadership experience at the U.S. Food and Drug Administration (FDA) and deep expertise in pharmaceutical regulatory policy to her client work. Elaine most recently served in a leadership role with the Office of Regulatory Policy within the Center for Drug Evaluation and Research (CDER). She is widely recognized as one of FDA's foremost legal authorities on postmarketing safety, including Risk Evaluation and Mitigation Strategies (REMS), safety labeling, and postmarketing requirements. She has worked closely with industry, clinicians, and patient groups to resolve complex regulatory challenges and shape national policy.

12:45 PM — 12:45 PM

Conference Adjourns