Baltimore Marriott Waterfront

Feb 05, 2024 7:00 AM - Feb 07, 2024 1:00 PM

700 Aliceanna Street , Baltimore, MD 21202

Global Pharmacovigilance and Risk Management Strategies Conference

Register for 2 or more short courses and save $150 off your registration fee!

Print Agenda

Day 1 Jan 24, 2024

10:00 AM — 2:00 PM

Short Course: Introduction to Statistics in Pharmacovigilance

Day 2 Feb 04, 2024

9:00 AM — 4:00 PM

Short Course: Aggregate Safety Assessment Planning (ASAP) Process

Session Chair(s)

Greg Ball, PhD

Safety Data Scientist
ASAPprocess, United States

Greg served in the Navy and taught HS math and physics before earning his PhD in biostatistics from the University of Texas. He co-led a crossfunctional company initiative at Merck to develop and implement the Aggregate Safety Assessment Planning (ASAP) process. His research on blinded safety monitoring procedures is being developed in collaboration with statistical and clinical scientists at several pharmaceutical companies (including AbbVie and Merck). Greg co-leads, with Mary Nilsson and Scott Proestel, the PHUSE Safety Analytics working group; he established (with Bill Wang) the ASA Biopharm Safety Monitoring working group; and he pioneered the joint DIA-ASA Interdisciplinary Safety Evaluation (DAISE) scientific working group.

Barbara Hendrickson, DrMed, MD

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

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

Day 3 Feb 05, 2024

7:30 AM — 8:30 AM | Ballroom VI - X

Networking Breakfast in the Exhibit Hall

8:30 AM — 8:40 AM | Ballroom V

Welcome & Opening Remarks

Welcome & Opening Remarks

Track: General Session

Session Chair(s)

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.

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.

8:40 AM — 9:25 AM Ballroom V

Session 1: Keynote: Personalized Medicine and the Pharmaceutical Industry

Keynote: Personalized Medicine and the Pharmaceutical Industry

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)

Speaker

Michael Ybarra, MD

Chief Medical Officer
Pharmaceutical Research and Manufacturers of America (PhRMA), United States

Michael Ybarra, MD, is Senior Vice President and Chief Medical Officer at the Pharmaceutical Research and Manufacturers of America (PhRMA). As an organization, PhRMA advocates for public policies that support the innovative biopharmaceutical ecosystem. Dr. Ybarra oversees coalition building, stakeholder engagement, and strategic partnerships in support of PhRMA's federal public policy priorities. Dr. Ybarra is an emergency physician and graduate of Stanford University and Georgetown University School of Medicine, where he also completed his residency training. He is an Assistant Professor of Emergency Medicine at Georgetown University School of Medicine where he continues to see patients in the emergency department.

9:25 AM — 10:10 AM Ballroom VI - X

Networking Break in the Exhibit Hall

9:35 AM — 10:05 AM DOVER AC

Hosted Session/Non-CE: Case Study Spotlight hosted by PharSafer®: Empowering Transformation: Tackling Concerns in Implementing Automated Safety Solutions

In today's fast-evolving pharmaceutical landscape, the adoption of automated safety solutions is quickly becoming ever more imperative for industry organisations aiming to achieve the highest levels of patient safety, regulatory compliance and operational efficiency.

Whilst the benefits of automation are evident for all to see, implementing such transformative changes can often raise concerns amongst those tasked with this activity – a taboo which we aim to eliminate through collaboration.

Within this session, we will perform a deep dive into the heart of these concerns and provide guidance on how to best overcome the perceived obstacles associated with delivering enhanced levels of patient safety through automation, and empower your organisation's journey towards a clearer, more compliant future, together.

Featured Topics:

- Clinical and post marketing drug safety
- AI and automation
- Patient and reporter engagement
- Safety data intake and case processing
- Safety database, process and systems optimisation
- Data accuracy and compliance
- Signal detection
- Risk management
- Periodic report writing
- Auditing and KPIs

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Speaker

Graeme Ladds, PhD

CEO & Owner
PharSafer, United Kingdom

10:10 AM — 11:25 AM

Ballroom V

Session 2: Updates on Policies, Guidances, and Regulations – North America

Session 2: Updates on Polices, Guidances and Regulations – North America

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
- Describe the use of FDA FMQs (FDA Medical Queries) and Standard Safety Tables and Figures
- Recognize post-market aspects of DILI risk assessment and RM approaches that aid in reporting data to the FDA

Track: General Session

Session Chair(s)

Scott Janiczak, PharmD, MPH

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

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

Joseph Paradis, PharmD

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

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

Robert Ball, MD, MPH, MSc

Deputy Director, Office of Surveillance and Epidemiology, CDER
FDA, United States

Robert Ball MD, MPH, ScM is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug and biologic product safety and effectiveness using Real World Evidence, including managing the Sentinel System.

Speaker(s)

FDA use of FMQs (FDA MedDRA Queries) and Standard Safety Tables and Figures

Y. Veronica Pei, MD, MEd, MPH

Acting Associate Director, Biomedical Informatics and Regulatory Review Science
FDA, United States

Dr. Veronica Pei is a board-certified emergency physician and a commissioned officer in the U.S. Public Health Service currently serving as Associate Director (Acting) of Biomedical Informatics and Regulatory Review Science team in the Office of New Drugs (OND), FDA. In this role, Dr. Pei is involved in development, implementation, and support of bioinformatics initiatives within OND. She is the current FDA topic lead for ICH M11 expert working group on the Structure and Content of Clinical Protocols. Dr. Pei is also the current lead for Standard Tables and Figures and Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of NASH guidance.

FDA Use of FMQs (FDA Medical Queries)

Scott Proestel, DrMed, MD

Senior Medical Officer, ODES, OND, CDER, FDA
FDA, United States

Scott Proestel, MD, is a Senior Medical Officer on the Biomedical Informatics and Regulatory Review Science Team at the US FDA's Center for Drug Evaluation and Research. He completed his internal medicine training at Johns Hopkins Hospital and obtained his medical degree from Columbia University College of Physicians & Surgeons. He has conducted and supervised clinical pre-market reviews of new drug and biologic applications at FDA, overseen HIV clinical trial conduct as an Office Director at the US National Institutes of Health, and supervised safety surveillance as a Division Director at FDA. His informatics research has included assessing the use of artificial intelligence to evaluate spontaneous safety reports submitted to the FDA.

Identification and Risk Management of Classic and Emerging DILI Phenotypes for New Drugs and Biological Agents: A Lifecycle Approach

Mark Avigan, MD

Associate Director for Critical Path Initiatives, OPE, OSE, CDER
FDA, United States

As a hepatologist and Associate Director in CDER's Office of Pharmacovigilance and Epidemiology, Dr. Avigan has been an expert consultant for the evaluation of drug-induced liver injury during the life cycle of drugs and biological agents. Earlier on, Dr. Avigan received his MD from McGill University. After his medical residency and GI fellowship, he served as an NIH staff fellow and then on the faculty of Georgetown University where he attended patients and was the principal investigator of NIH-funded grants to elucidate basic mechanisms in cell growth pathways. Dr. Avigan participates in public-private partnerships supporting innovation in the analysis of hepatotoxicity associated with pharmaceuticals and biological agents.

Pre-Market Challenges in DILI Risk Assessment and RM Approaches

Paul Hayashi, MD, MPH

Physician Lead, DILI Team, Division of Hepatology and Nutrition,OND, CDER
FDA, United States

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

11:25 AM — 12:25 PM Ballroom VI - X

Networking Luncheon in the Exhibit Hall

11:40 AM — 12:25 PM

Roundtable Discussions

Join colleagues to discuss the topics that matter most to you! Attendees will have the opportunity to sign up for a roundtable of your choice via the conference app (releasing January 11th – announcement will be sent via email when access is available). Roundtables are first come first serve.

Roundtable topics to include:

- The potential for greater alignment of REMS and aRMM in complex risk minimisation scenarios hosted by Mark Perrott
- Implementation of the FDA Medical Queries - hosted by Barbara Hendrickson and Scott Proestel
- FDA use of Standard Safety Tables and Figures - Y. Veronica Pei
- What are the challenges of implementing intelligent automation in Pharmacovigilance? hosted by Nicole Baker
- Managing complexities in ICSR reporting hosted by Brian Edwards
- Recent Pharmacovigilance Audit/Inspection Findings hosted by Janine Gavin-Poulter
- Medical Devices: Challenges in keeping pace with Evolving Regulatory Landscape for Clinical and Post-Marketing Device Vigilance hosted by Vineet Kacker

Navigating the Nexus: Evidence-Based Medicine in Pharmacovigilance hosted by Tarek Hammad

Session Chair(s)

Representative Invited

DIA, United States

this is a test

12:25 PM — 1:40 PM

Ballroom V

Session 3: Updates on Policies, Guidances, and Regulations – Europe

Representatives from the European Medicines Agency & Medicines & Healthcare products Regulatory Agency will provide regulatory and pharmacovigilance updates from Europe and the UK. We will hear from the two regulatory authorities on their current and upcoming work priorities with a focus on advances in pharmacovigilance and risk management strategies.

Learning Objective :

- Describe recent EMA regulatory updates including Good Vigilance Practice guidance updates & its implications for pharmacovigilance activities
- Describe recent MHRA regulatory updates and advances at the MHRA in pharmacovigilance and risk management strategies at the MHRA
- Discuss current challenges and future opportunities for safety reporting from a regulatory perspective

Track: General Session

Session Chair(s)

Sarah Vaughan

Head of Vigilance Operations
Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Sarah has worked in pharmacovigilance at the MHRA for the past 15 years, her current role is the Head of Vigilance Operations, responsible for adverse incident collection & signal management for medicines and medical devices. Sarah is currently leading on the development and transformation of the Agency's vigilance systems for all medicinal product types.

Speaker(s)

Speaker

Emil Andrei Cochino, MD, MHS

Scientific Senior Specialist (Risk Management)
European Medicines Agency, Netherlands

Dr Emil Andrei Cochino is a Specialist in Public Health and Health Services Management. He has been a scientific officer at EMA from 2009, and is working in the Human Medicines Department as a Scientific Senior Specialist (Risk Management), where he is responsible for peer-reviewing risk management plans for centrally authorised products (ATMPs and vaccines) and improving the access of ATMPs to the market by supporting the collaboration with the HTA and payers organisations. Furthermore, he has overseen the revision 2 update of GVP Module V – Risk Management Systems and coreRMP19 guidance.

Panelist – Virtual

Georgy Genov, MD

Head of PHV Office, ad-interim Head of Quality & Safety of Medicines Department
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.

Speaker

Phil Tregunno

Deputy Director - Patient Safety Monitoring
Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Phil is the Deputy Director of Patient Safety Monitoring within MHRA's Safety & Surveillance function and has over twenty years of experience working in pharmacovigilance. Prior to his current role Phil spent fourteen years leading and developing the pharmacovigilance system, including technology, processes, and relevant aspects of Pharmacovigilance Legislation. He is now accountable for Patient Safety Monitoring across medicines, vaccines, devices, defects and blood products. Phil was responsible delivery of MHRA systems for COVID-19 vaccine surveillance and their integration into the healthcare system. For several years he has led international projects to develop and deliver tools for global pharmacovigilance.

1:40 PM — 2:25 PM Ballroom VI - X

Networking Break in the Exhibit Hall

2:25 PM — 3:40 PM Ballroom V

Session 4: Updates on Policies, Guidances, and Regulations – Asia

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 pharmacovigilance regulations in India through development to post-approval and the recent GVP inspection trend
- Explain what is required to do to comply with the pharmacovigilance requirements in China/Japan and key challenges
- Explain the increasing requirement for pharmacovigilance system master files or similar documents in Asian countries and compare the contents with the EU PV system master file

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.

Yijing (Hellen) Zhang, MPharm

Executive Director, Global Patient Safety
Beigene, China

Executive Director head of Individual Case Safety, Medical Review & Aggregate Safety Reporting team, PV responsible person in China.

Speaker(s)

PV & Risk Management in India

Raza Mohammed, MD

Chief Scientific Officer

OrciMed Life Science Private Limited, India

Raza Mohammed is a physician by training and represents as Chief Scientific Officer at OrciMed Life Sciences. He is qualified as a diabetologist and pharmacologist and graduated from India. He has 15 years of experience in pharmacovigilance and over 10 years in clinical practice. Raza began his career in the industry with Novartis and later went on to co-establish Vigi Medsafe, a PV service provider company where he worked as the Director of Medical Affairs. He subsequently worked as a Senior Medical Director at PPD. Raza is a subject matter expert, and his experience involves leading and managing medical teams, clinical and post-marketing pharmacovigilance, aggregate reports, risk management plans, signal management, RA queries and audits.

3:45 PM — 5:00 PM Ballroom V

Session 5: Safety Management Considerations for Advanced Therapeutics

Session 5: Safety Management Considerations for Advanced Therapeutics

Learning Objective : In this session you will hear experiences, insights, and perspectives from those working in this field.

- Identify specific challenges for adequate safety monitoring for advanced therapeutics
- Gain insights on how to improve your acumen on advanced therapies for your everyday work

Track: General Session

Session Chair(s)

Mariette Boerstoel-Streefland, MD, MBA, MS

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

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

Speaker(s)

Gene Therapy for Duchenne Muscular Dystrophy: Lessons learned (so far) from the fordadistrogene

movaparvovec clinical trial program

Kasia Lobello, MD

Safety Risk Lead
Pfizer Inc., United States

Kasia Lobello is a Senior Director and Safety Risk Lead in Pfizer's Safety Surveillance and Risk Management group. Kasia received her undergraduate training in neurobiology from Cornell University, followed by a medical degree from the University at Buffalo School of Medicine and Biomedical Sciences. She completed residency training in Neurology at Duke University. Since joining Wyeth/Pfizer in 2007, Kasia has held a variety of roles in both Clinical Development and Safety, focusing on neurologic disorders.

Safety Management Considerations for Advanced Therapeutics

Emil Andrei Cochino, MD, MHS

Scientific Senior Specialist (Risk Management)
European Medicines Agency, Netherlands

Dr Emil Andrei Cochino is a Specialist in Public Health and Health Services Management. He has been a scientific officer at EMA from 2009, and is working in the Human Medicines Department as a Scientific Senior Specialist (Risk Management), where he is responsible for peer-reviewing risk management plans for centrally authorised products (ATMPs and vaccines) and improving the access of ATMPs to the market by supporting the collaboration with the HTA and payers organisations. Furthermore, he has overseen the revision 2 update of GVP Module V – Risk Management Systems and coreRMP19 guidance.

Speakers

Robert Sokolic, MD, FACP

Medical Officer
Food and Drug Administration, United States

5:00 PM — 6:00 PM Ballroom VI - X

Networking Reception in the Exhibit Hall

Day 4 Feb 06, 2024

7:00 AM — 8:00 AM Ballroom VI - X

Networking Breakfast in the Exhibit Hall

8:00 AM — 9:15 AM

Ballroom V

Session 6: Application and Use of Machine Learning, Artificial Intelligence, Automation, and Technology in Pharmacovigilance

This session will discuss use cases for Analytical/traditional AI and Generative AI and analyze the opportunities for expanding its' impact/use. We will look at the impact of digital health on pharmacovigilance and forces at play with it's ongoing impact. Lastly, we will explore ChatGPT for Safety professionals.

Learning Objective :

- Develop an understanding of the practical uses of Analytical and Generative AI in pharmacoviglinace
- Acquire targeted knowledge to evaluate and apply ChatGPT's capabilities within the context of safety operations
- Leave with a clear framework for assessing the impact of Digital Health on Pharmacovigilance, including its benefits and challenges

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.

Speaker(s)

Digital Health: A BooM or Burden to Pharmacovigilance?

Sibel D. Guerler, MSc

Head, Innovation, Partnerships & Process Optimization, WorldWide Patient Safety
Bristol-Myers Squibb Company, Switzerland

As a neurobiologist with a penchant for rebellion, Sibel has committed the past 15 years to progressing patient safety. Now, in her role in WorldWide Patient Safety at Bristol Myers Squibb, she focuses on nurturing an innovative culture, upskilling people, identifying the right problems to solve while seeking to break new ground with data, models and digital health solutions.

Use cases for Analytical/traditional AI and Generative AI: Where are the opportunities?

Tracey Boone, MBA

Director
AbbVie, United States

Tracey Boone holds a BS in biology, an MBA and has been an ASCP-certified medical technologist for 30 years. Before joining pharma, she worked in a hospital laboratory for 10 years. Tracey started her pharma career with Pfizer and worked for 11 years in various scientific, technical and management positions in non-clinical R&D. Tracey has been with AbbVie for 13 years, holding positions in Diagnostics, Regulatory Operations, and Pharmacovigilance. For the past 8 years, Tracey has led initiatives to improve efficiency through robotic process automation and AI. Currently, Tracey is the business lead for several proof-of-concepts for the use of AI, ML, and LLMs in aggregate reporting, signal identification, and data review.

9:15 AM — 10:00 AM

Networking Break in the Exhibit Hall

9:25 AM — 9:55 AM DOVER AC

Hosted Session/Non-CE: Case Study Spotlight hosted by Caidya: Challenges and Opportunities with Safety Management and Reporting in Multinational Studies

As safety regulations and guidances are updated, Pharmacovigilance staff must remain aware of key differences to plan effectively, provide high quality reports, and ensure compliance with all timelines. This case study will provide example differences in national and regional requirements encountered in a multinational clinical trial involving safety data collection, serious adverse event (SAE) assessment, expedited and periodic reporting. Diligent regulatory intelligence and good team communication led to more robust study planning and Safety Management Plans. Periodic review of processes and plans continued to be needed as the study progressed

Featured Topics:

- Ensuring diversity of clinical trials while remaining compliant with data protection requirements
- Performing casuality and expectedness assessments of SAEs
- Implementing ICH E2B (R3) regional elements
- Registering and using regulatory reporting portals
- Incorporating national and regional expectations into Development Safety Update Plans (DSURs)

Session Chair(s)

Representative Invited

United States

Speaker(s)

Instructor

Sharon Moore, MD, MBA, MPH

Chief Medical Officer
Caidya, United States

Dr. Moore is Global Head, Quality Assurance at Chiltern. Experience: Medical Affairs, Pharmacovigilance, internal medicine practice, investigator and IRB member. Education: MD (Vanderbilt University), MBA (East Tennessee State University), and MPH (Medical College of Wisconsin). Certification: CPI.

10:00 AM — 11:15 AM Ballroom V

Session 7: Insights on Benefit-Risk Assessment

The CIOMS WG XII Benefit-Risk report was released, outlining the benefit-risk (BR) landscape and promoting the use of a structured BR framework (SBRF) from the beginning and continuously updated and applied throughout the product lifecycle, including key decision-making steps. This will enable a shift from evaluating BR from unstructured ways towards a more structured, transparent multi-stakeholder approach. Also, it advocated for including patient-centric endpoints that capture both benefit and risk in clinical trial designs. Members from CIOMS WG XII will provide an overview of this document, and panelists will be invited to share insights from different perspectives.

Learning Objective :

- Describe the key recommendations from the CIOMS WG XII Benefit-Risk report
- Recognize the gaps between the current practice and the recommendations from the CIOMS WG XII Benefit-Risk report
- Prepare to implement relevant components from the CIOMS WG XII Benefit-Risk report in day job
- Deploy a multi-functional team for structured benefit risk assessment

- Initiate internal conversations to facilitate incorporating patient input to inform SBRF

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.

Jeremy Jokinen, PhD, MS

Vice President and Head, Safety Evidence and Sciences
Bristol-Myers Squibb Company, United States

Jeremy Jokinen is the Vice President and Head, Safety Evidence and Sciences at Bristol Myers Squibb. In this role, he leads a global team of risk management, epidemiology, and safety science experts responsible for insights, evidence generation, and risk minimization programs ensuring the safety of patients worldwide. 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

Speaker(s)

CIOMS Working Group (WG) XII Report: Overview and Chapter II-Structured BR Approach/Framework

Hong Yang, PhD

Biologist, OBPV, CBER
FDA, United States

Dr. Hong Yang is a senior advisor for benefit-risk assessment in OBPV/CBER/FDA. She holds Ph.D. degree in Biological Engineering. Dr. Yang has expertise in benefit-risk assessment of biological products and Modeling and Simulation to inform drug development. She has been devoted in regulatory review, as well as research, training and outreach activities for novel approaches to benefit-risk assessment. She led many benefit-risk assessments to inform FDA regulatory decision and participated development of guidance for industry. She is a member of several FDA, HHS, WHO, CIOMS and ASA working groups on benefit-risk assessment of medical products.

CIOMS Working Group (WG) XII Report: Chapter III-BR Methodology Considerations

Richard Forshee, PhD

Deputy Director, OBPV CBER
FDA, United States

Richard Forshee is the Deputy Director for the Office of Biostatistics and Pharmacovigilance in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of blood and blood products, vaccines, and human cell and tissue products. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.

Speakers

Susan Colilla, PhD, MPH

Epidemiology Leader
Teva Pharmaceuticals, United States

Susan is currently at Teva Pharmaceuticals leading its Epidemiology group which provides RWE for Clinical Development, Medical Affairs and PV groups. In 2022, she established a Benefit-Risk Assessment Planning Process at Teva to be used for products from early development stage to post-marketing. Prior to that she was at CSL Behring where she was the Clinical Epidemiology Team Lead and developed an SOP for Benefit-Risk Assessment throughout the drug lifecycle. She has also worked in Epidemiology & Benefit Risk Evaluation and PV groups at Sanofi for over 3 years in rare disease, immunology and neuroscience. She received a Ph.D. in Epidemiology from Univ of Illinois School of Public Health and an MPH from Emory University.

Panelist

Brian Edwards, DrMed

Vice President
International Society of Pharmacovigilance, United Kingdom

After his training in hospital medicine and clinical research for 14 years, Dr. Edwards joined the UK Medicines Control Agency (MHRA) in 1994 where he had various responsibilities as a pharmacovigilance assessor. In 1999 he joined Parexel to become Senior Medical Director before joining J&J as a deputy QPPV in 2005. In addition he is Director of ISoP Secretariat Ltd, ISoP Board Member and VP in the Alliance Clinical Research Excellence and Safety (ACRES) . He chairs the unique Pharmaceutical ergonomics & human Factors Group in the UK. After 14 years at NDA Regulatory Science Ltd, he has his own pharmacovigilance consultancy Husoteria Ltd

11:20 AM — 12:35 PM

Ballroom V

Session 8: Risk Management, Past, Present and Future?

This session will review the evolution of risk minimization requirements and solutions since the inception of formal regulations. It will review approaches that have been, and could be used to address the objectives of risk evaluation and mitigation strategies (REMS) and additional risk minimization measures (aRMMs), particularly in the context of learnings from shared approaches for generic and biosimilar products. Current challenges to effective implementation will be examined in a global context, and the potential for a future which increases the focus on patient need and value, while still addressing compliance requirements, will be explored.

Learning Objective :

- Describe the pharmaceutical industry's current approaches to REMS/aRMMs
- Express options for the management of complex risk minimization commitments by generics companies
- Discuss the improvement opportunities in the implementation of risk management programs
- Understand how digital approaches can support the development of more patient-centric approaches to improving risk management

Track: General Session

Session Chair(s)

Mark Perrott, PhD

Axian Consulting Limited, 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.

Speaker(s)

The evolution of risk management in REMS, where did we start? how far have we come?

Yasmeen Abou-Sayed, PharmD

Team Leader
FDA, United States

Dr. Yasmeen Abou-Sayed is a Team Leader in the Division of Risk Management in the Office of Surveillance and Epidemiology in the Center for Drug Evaluation and Research at the FDA. She oversees a team of Risk Management Analysts (RMA), to provide expertise on the potential need, development, and modification of risk evaluation and mitigation strategies (REMS). Dr. Abou-Sayed was previously an RMA at FDA and worked 10 years as a staff pharmacist and pharmacy manager for CVS in Maryland and New York. She maintains a part-time role with CVS, working as a community pharmacist and administering vaccinations. Dr. Abou-Sayed received her PharmD from the University of Maryland at Baltimore and completed undergrad at the University of Houston.

Risk Management – Compliance Activity or Contributor to Benefit-Risk?

Michael Forstner, PhD, MPH, MSc

Head of Global Safety Science
SOBI, Switzerland

Michael's main focus areas are the planning, development, implementation and evaluation of benefit-risk management solutions, as well as the optimization of processes around 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.

On the horizon for global risk management, better value for stakeholders and better outcomes

Sherice Mills

President and CEO
Adroit Risk Management, LLC, United States

12:35 PM — 1:35 PM Ballroom VI - X

Networking Luncheon in the Exhibit Hall

12:45 PM — 1:30 PM

Sponsored Roundtable Discussions

Join colleagues to discuss the topics that matter most to you! Attendees will have the opportunity to sign up for a roundtable of your choice via the conference app (releasing January 11th – announcement will be sent via email when access is available). Roundtables are first come first serve.
Roundtable 1 Hosted by PPD, part of Thermo Fisher Scientific: Future of the PV workforce with automation and technology.

- This roundtable will discuss training, task and compensate shifts of staff for the future in PV technology automation.

Roundtable 2 Hosted by Digital Science & Research Solutions Inc

Roundtable 3 Hosted by Ultragenic Research and Technologies LLC

Track: General Session

Session Chair(s)

Representative Invited

DIA, United States

this is a test

Speaker(s)

Roundtable 1 Hosted by PPD, part of Thermo Fisher Scientific: Future of the PV workforce with automation and technology.

Lindsay Leming

Sr. Director, Pharmacovigilance
PPD, part of Thermo Fisher Scientific, United States

Roundtable 1 Hosted by PPD, part of Thermo Fisher Scientific: Future of the PV workforce with automation and technology.

Jennifer White

Director PV
PPD, United States

1:35 PM — 2:50 PM

Ballroom V

Session 9: Use of Real-World Data and Real-World Evidence in Safety

This session will explore ways in which real-world data can be applied to questions that typically require the conduct of a randomized controlled clinical trial. In the absence of robust epidemiological data or appropriately sized control groups from clinical studies, it can be difficult to establish background rates for various adverse events of interest. However, real-world data can offer insight into these rates when used to create synthetic control groups. Causal inference techniques can be applied to observational data in an attempt to emulate a hypothetical pragmatic randomized trial. In addition, combining real-world evidence with clinical trial data can be a method to develop personalized benefit-risk assessments.

Learning Objective :

- Identify ways in which real-world data can support safety surveillance programs

- Understand how causal inference models can evaluate safety questions for which no randomized controlled clinical data exist
- Describe the concept of a synthetic control group
- Discuss how real-world evidence and clinical trial data can be used to predict which patients stand to gain the most from therapy

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)

An overview of target trial emulation and benchmarking

Sara Lodi, PhD

Associate Professor, Biostatistics
Boston University School of Public Health, United States

Sara Lodi is an Associate Professor of Biostatistics at the Boston University School of Public Health. She obtained her PhD in Medical Statistics at the London School of Hygiene and Tropical Medicine in 2009, UK. Her research focuses on causal inference methods for observational studies using big data, methods for causal inference to improve the statistical analysis of clinical trials, and the reconciliation of results from clinical trials and observational studies, mainly in the areas of infectious diseases (HIV, hepatitis C, tuberculosis) and substance use disorder.

Use of Real-World Evidence in Personalized Benefit Risk Assessment

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

Vice President, Head of Medical Safety, Marketed Products
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.

RWD and Safety Signal Detection

Israel Gutierrez, MD

Chief Medical Officer
TLR Therapeutics Inc, United States

Currently the Chief Medical Officer, TLR Therapeutics Inc. Israel is a Global Biotech Executive with over 25 years of experience building multi-therapeutic area medical affairs, clinical development, and drug safety. He has been working with multiple companies in many layers of executive management in the areas of Drug development, Risk Management, Artificial Intelligence implementation and PV Strategy. He has provided leadership of multifunctional groups across many companies including PRA Health Sciences, Pharmacyclics, Abbvie, Exelixis, Genentech, Roche Ltd, Celgene, Pharmion Corp, and Mankind corp. He is a Fellow of the Royal Society of Medicine and a Fellow of the Royal Society of Public Health.

2:50 PM — 3:20 PM Ballroom VI - X

Networking Break in the Exhibit Hall

3:20 PM — 4:35 PM Ballroom V

Session 10: Insights into the Collection of Safety Data in Pregnancy

This session will focus on enhancing the collection of informative safety data on drug and vaccine use in pregnancy. Points that will be covered include:

- Ethical and scientific considerations for inclusion of pregnant women in clinical trials
- Novel approaches to collecting safety data about vaccine use in pregnancy (e.g. COVID vaccines, new RSV vaccine approved in August 2023)
- Core data elements for pregnancy pharmacovigilance studies using primary source data collection methods

Learning Objective :

- Explain the ethical issues of both the exclusion and inclusion of pregnant women in clinical trials
- Describe the challenges and advancements of inclusion of pregnant women in clinical trials to generate primary data
- Identify the key data required to enable evaluation of the safety of a drug administered in pregnancy

- Discuss lessons learned regarding prior approaches to safety data collection following vaccination or drug use in pregnancy

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 19 years of pharmaceutical industry experience. Dr. Hendrickson has been involved in multiple new product and additional indication submissions. She also has participated in several clinical trial safety initiatives related to implementation of internal data monitoring committees and IND aggregate safety reporting procedures. In addition, she co-leads the DIA-ASA Aggregate Safety Assessment Planning Working Group.

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.

Speaker(s)

Ethical Considerations for the Collection of Safety Data in Pregnancy

Anne Drapkin Lyerly, MD, MA

Professor, Social Medicine Research; Professor, Obstetrics and Gynecology
University of North Carolina, United States

Dr. Lyerly is a Professor of Social Medicine, Research Professor of Obstetrics and Gynecology, and Core Faculty in the Center for Bioethics at UNC-Chapel Hill. A board-certified obstetrician-gynecologist, her work addresses morally complex issues at the intersection of ethics, reproduction, and health policy. She has led NIH-funde projects developing ethics guidance for research in pregnancy. She is a former Chair of the ACOG Committee on Ethics, and has served as advisor to US NIH, CDC, FDA and WHO. She is a fellow of the Hastings Center, and a member of the

Johns Hopkins Society of Scholars. She has written dozens of articles and book chapters and is the author of A Good Birth, published by Penguin/Random House.

CDC COVID-19 Vaccine Pregnancy Registry: Experience and Lessons Learned

Christine Olson, MD, MPH

Medical Officer, Immunization Safety Office/DHQP/NCEZID
Centers for Disease Control and Prevention, United States

Captain Christine Olson, MD, MPH, is board-certified in Obstetrics & Gynecology and Preventive Medicine and is a US Public Health Service medical officer in CDC's Immunization Safety Office. Prior to joining CDC, she was a clinical assistant professor and clerkship director of ob/gyn. She's worked at the local, state, and international levels of public health in both the infectious and chronic disease areas, including in outbreak and emergency response, immigrant and refugee health, maternal morbidity and mortality prevention, preterm birth and infant health, occupational health, and vaccine safety. Since 2021, she's led CDC's COVID-19 Vaccine Pregnancy Registry.

Medication and Pregnancy - Improving safety data collection, data harmonisation and risk communication using outputs from the IMI ConcePTION project

Jonathan Luke Richardson, PhD

Principal Medical Information Scientist and Data Manager, UK Teratology Informat
UK Teratology Information Service, United Kingdom

Dr Richardson (PhD) is the Principal Medical Information Scientist and Data Manager at the UK Teratology Information Service. He has worked at UKTIS since 2009, completing a PhD whilst with the service investigating novel methods of teratogen surveillance. His main research interests include improving teratogen surveillance data collection techniques, international collaborative approaches to data collection and harmonisation through the application of common data models and the development of data collection and reporting standards in pregnancy pharmacovigilance, and risk communication/informatics relating to medication use in pregnancy.

4:35 PM — 7:00 PM Ballroom V

Adapting to Generative AI: Changing PV Landscapes

This discussion will bring together three distinguished experts to illuminate the transformative impact of regenerative AI on Pharmacovigilance (PV). The central inquiry revolves around envisioning the future: "How will the PV landscape change, and what must drug safety professionals do to stay relevant in a world of Generative AI?"

Click here for more information.

Session Chair(s)

Representative Invited

DIA, United States

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Day 5 Feb 07, 2024

7:30 AM — 8:30 AM Ballroom VI - X

Networking Breakfast in the Exhibit Hall

8:30 AM — 9:45 AM Ballroom V

Session 11: Signal Detection and Evaluation

New methods of detecting safety signals are evolving. This session will explore novel ways in which safety signals may be identified within social media postings as well as the use of large language models to detect adverse events within clinical notes from electronic health records. The results from a horizon scan will be summarized concerning the use of AI tools and natural machine learning for safety surveillance in the absence of a REMS as well as the use of real-world data (RWD) by Sentinel for signal detection.

Learning Objective :

- Understand the application of disproportionate reporting rate algorithms to the evaluation of social media sources of adverse event information
- Describe how large language models can be applied to detecting adverse events from electronic health information
- Discuss how Sentinel utilizes real-world data for signal detection
- Explain how AI and natural machine learning tools can assist in safety surveillance in the absence of a REMS

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)

Social media safety monitoring: Emergence of a new global tool for early signal detection? Experience from the COVID-19 vaccine

Patrick M. Caubel, MD, PhD, MBA

Chief Safety Officer
Pfizer Inc, United States

Patrick Caubel is Chief Safety Officer and Global Head of Worldwide Safety for Pfizer . Patrick earned his M.D. degree, with specialization in Gynecology, Obstetrics and Oncology, from the University of Paris XIII (France), followed by a Ph.D. in Clinical and Experimental Pharmacology from the University of Paris VII (France) and later a M.B.A from Rutgers University. He worked in positions of increasing responsibility first in academia, and subsequently for Merck KgaA, Johnson & Johnson and Sanofi. Pfizer Worldwide Safety is in charge of safety monitoring and reporting for all Pfizer products around the globe. Patrick has been actively involved in COVID vaccine and antivirals development and safety monitoring during the COVID-19 pandemic.

Automated Adverse Event Detection from Electronic Health Records using Large Language Models

Vivek Rudrapatna, MD, PhD

Assistant Professor; Co-Director, Center for Real-World Evidence
UC San Francisco, United States

Vivek Rudrapatna is a gastroenterologist and an assistant professor at UC San Francisco. His research focuses on methods for analyzing large clinical datasets to improve decision making in healthcare. He is also a co-director of the UCSF Center for Real-World Evidence. In this role, he facilitates research collaborations between government, industry, and academia, particularly those that involve the analysis of electronic health records data.

A Horizon Scan Perspective on the use of AI and Real-World Data for Signal Detection

Ariela G Chick, MPH

Senior Strategic PV Advisor
Perspective PV, United States

Ariela Chick has worked in Pharmacovigilance for over 20 years and has held leadership roles in global safety operations, PV training & compliance, safety vendor management and REMS/PASS program management. She has been a PV Leader at global companies like Amylin, BioMarin, Gilead Sciences and BeiGene and has successfully supported teams with successful global PV & GCP inspections. As a PV Strategic Advisor/consultant for the past few years, Ariela has enjoyed preparing teams for the increased PV demands that accompany entry into the commercial phase. Ariela holds her B.S. degree in Biological Sciences from UC Irvine, and her MPH in Infectious Diseases from UC Berkeley.

Signal Detection for Clinical Trial Design: Finding the Right Questions

Peg Fletcher, MD, PhD

President
MedAssessment, Inc., United States

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

9:45 AM — 10:05 AM Ballroom VI - X

Networking Break in the Exhibit Hall

10:05 AM — 11:20 AM Ballroom V

Session 12: Implementation of Safety Surveillance Plans Roundtables

This session will focus on the logistics of implementing the Safety Surveillance Plan (SSP) described in FDA's June 2021 Draft Guidance, Sponsor Responsibilities— Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies.

After a brief introduction of the topic, participants will be divided into separate groups with a facilitator and discussion prompts. Participants will be asked to converse about how the various components of the FDA's suggested SSP are best implemented. After a period of time, the participants will come back together and share the insights from their table discussion.

Learning Objective :

- Describe the components of FDA's suggested Safety Surveillance Plan per their June 2021 Draft Guidance
- Appraise different approaches to implementing a Safety Surveillance Plan
- Identify challenges in execution of the Safety Surveillance Plan and potential ways to overcome

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 19 years of pharmaceutical industry experience. Dr. Hendrickson has been involved in multiple new product and additional indication submissions. She also has participated in several clinical trial safety initiatives related to implementation of internal data monitoring committees and IND aggregate safety reporting procedures. In addition, she co-leads the DIA-ASA Aggregate Safety Assessment Planning Working Group.

Speaker(s)

Speaker

Cynthia McShea, MPH

Head, Safety Statistics
UCB Biosciences, United States

Cindy McShea received a BS in Mathematics from East Carolina University in North Carolina, USA and completed an MPH in Biostatistics from the University of North Carolina at Chapel Hill in North Carolina, USA. Cindy is a senior director of Biostatistics at UCB Biosciences where she leads the Safety Statists team within the Biometrics and Quantitative Sciences group. She has over 25 years of experience in the pharmaceutical industry, 20 of which have been spent in statistical and leadership roles within late phase clinical development in neurology and immunology therapeutic areas. She is a contributing member of the Drug Information Association-American Statistical Association Aggregate Safety Assessment Planning Task Force.

Speaker

Greg Ball, PhD

Safety Data Scientist
ASAPprocess, United States

Greg served in the Navy and taught HS math and physics before earning his PhD in biostatistics from the University of Texas. He co-led a crossfunctional company initiative at Merck to develop and implement the Aggregate Safety Assessment Planning (ASAP) process. His research on blinded safety monitoring procedures is being developed in collaboration with statistical and clinical scientists at several pharmaceutical companies (including AbbVie and

Merck). Greg co-leads, with Mary Nilsson and Scott Proestel, the PHUSE Safety Analytics working group; he established (with Bill Wang) the ASA Biopharm Safety Monitoring working group; and he pioneered the joint DIA-ASA Interdisciplinary Safety Evaluation (DAISE) scientific working group.

Speaker

Ranjeeta Sinvhal, MD

Executive Medical Director, Medical Safety
AbbVie, United States

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

Speaker

Evgeny Zalmover

Executive Director, Medical Safety, Oncology, Patient Safety and Pharmacovigilan
Boehringer-Ingelheim Pharmaceuticals, Inc., United States

Evgeny Zalmover is an Executive Director, leading a team of patient safety physicians within the Oncology Therapeutic area of the Global Patient Safety and Pharmacovigilance department at Boehringer Ingelheim Pharmaceutical, Inc. since 2022. Evgeny is a medical doctor with 6 years of clinical practice (general and endocrine surgery) and over 17 years of pharmacovigilance experience working on cross functional teams with increasing roles and responsibilities at Schering-Plough, Merck & Co, US (aka MSD) and Sanofi. In his current position, Evgeny holds full medical strategic accountability for the benefit-risk and risk minimization activities for a portfolio of core strategic assets on a global level.

11:20 AM — 11:40 AM Ballroom VI - X

Networking Break in the Exhibit Hall

11:40 AM — 12:55 PM Ballroom V

Session 13: The World is Changing, How do We Adapt?

The world of pharmacovigilance requires new skills and the ability to adapt to a rapidly changing environment. Speakers in this session will discuss a case study of individual skills identification and assessing readiness for change as well as provide an introduction to organizational change management. Finally, speakers will consider the good and bad of leadership through change using examples from recent change management initiatives. Topics will be covered in both lecture and small group exercises.

Learning Objective :

- Understand individual skills assessment and readiness for change
- Apply a tool to facilitate organizational change management
- Discuss successes and pitfalls of change management in teams and organizations

Track: General Session

Session Chair(s)

Jeremy Jokinen, PhD, MS

Vice President and Head, Safety Evidence and Sciences
Bristol-Myers Squibb Company, United States

Jeremy Jokinen is the Vice President and Head, Safety Evidence and Sciences at Bristol Myers Squibb. In this role, he leads a global team of risk management, epidemiology, and safety science experts responsible for insights, evidence generation, and risk minimization programs ensuring the safety of patients worldwide. 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

Annette S. Williams, MBA, RPh

Vice President, Pharmacovigilance
IQVIA, United States

Annette Williams, M.B.A. R.Ph, is Vice President, Global Head of Lifecycle Safety, leading IQVIA's comprehensive Safety organization, consisting of more than 4,000 professionals worldwide, providing services across the PV spectrum, including: case processing, regulatory reporting, aggregate reporting, signal detection, risk management, medical information, local affiliate PV support and safety systems. Williams oversees the development and adoption of innovative technologies to streamline the management of safety information and subsequent data analytics. Prior to IQVIA, she held leadership positions in both CRO and Pharma fields, including Drug Safety Alliance, Teamm Pharmaceuticals, and GSK.

Speaker(s)

Building Future Focused PV professionals Through Skills Development and Multidirectional Career Pathways

Anjali Shah, PharmD

Executive Director, Business Capabilities and Innovation, WWPS
Bristol-Myers Squibb Company, United States

Anjali Shah, PharmD has 15+ years experience in the biopharmaceutical industry in a variety of therapeutic, operational and leadership roles across Medical Affairs and Patient Safety. Inspired by the opportunity to enable safe and informed use of medicines, Anjali is currently involved with establishing and growing a new Capabilities and Innovation function within Worldwide Patient Safety at Bristol Myers Squibb to drive the next generation of Patient Safety.

Change Management

Megan McNeal

Director, Strategic Operations
IQVIA, United States

Megan McNeal is a Director of Strategic Operations in the Data Sciences, Safety and Medical functions of IQVIA, where she is responsible for Change Management and Lean Six Sigma Process Improvement. Prior to transitioning to this role, Megan spent 18 years in a variety of operational and leadership roles in Data Management, mostly at IQVIA. She leverages her knowledge and experience to drive digital transformation efforts across the organization, all the while supporting their #1 resource - their people. Megan earned her Bachelors of Biology from UMKC, holds a Prosci Change Facilitator certification and a Lean Six Sigma black belt from the University of Kansas.

12:55 PM — 1:00 PM Ballroom V

Closing Remarks

Closing Remarks

Session Chair(s)

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.

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.

Day 6 Feb 27, 2024

10:00 AM — 2:00 PM

Short Course: Good Pharmacovigilance Practices (GVP) Operations Development – From Clinical Trial to Post Marketing

Session Chair(s)

Catherine Baldridge, MSc

Head of Safety
Fusion Pharmaceuticals, United States

Catherine Baldridge is the Sr. Director of Global Safety and Pharmacovigilance, Head of Safety, at Fusion Pharmaceuticals. She has more than 20 years of experience and serves as an executive consultant to the industry providing leadership and support in Pharmacovigilance Operations, development, training, regulatory, and inspection readiness. She has a Bachelors degree in Neuro Psychology from Hollins University and a Masters of Science in Clinical Investigation and Patient Research from the University of Virginia. Catherine was a former adjunct faculty member at Temple University, teaching several courses in pre and post marketing safety and Pharmacovigilance, and former chair of the DIA Clinical Safety and Pharmacovigilance Community.