DIA

Global Pharmacovigilance and Risk Management Strategies Conference

Short Courses: January 10, 12, 14 | Conference: January 24-26 | Virtual

Overview

For pharmacovigilance professionals, the complexity of monitoring safe medicinal practices are heightened by the rapid development of multiple vaccines and treatments, the emergent nature of knowledge regarding COVID-19, and pervasive misinformation about prevention and treatment practices. Current challenges will have lasting impacts on safety, pharmacovigilance, risk management, and more.

DIA's *Global Pharmacovigilance and Risk Management Strategies Conference* was developed by recognized experts from the biopharmaceutical industry and global regulatory agencies. This conference provides the background, context, and opportunities to discuss current challenges alongside fresh problem-solving strategies that matter most to professionals working in the field.

2022's PV Conference invites stakeholders from medicines research, global regulation, and healthcare to join and analyze current challenges for safety in pharmacovigilance efforts and examine effective strategies for addressing gaps and needs. These new approaches and collaborations build on the foundation of sound pharmacovigilance principles to optimize safety and pharmacovigilance practice and ensure safe medicines for patients in a global and regional context.

Highlights

Earn while you Learn at the 2022 Global Pharmacovigilance and Risk Management Strategies Conference!
Opportunity to win a $300, $200 or $100 gift card! How to win:

1. Update your email address within the DIA GPVRMS Platform
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Three Short Courses:

- **January 10 - Short Course 1:** Reference Safety Information
- **January 12 - Short Course 2:** Aggregate Safety Assessments
- **January 14 - Short Course 3:** Getting Real About Inspections

PROGRAM CHAIRS

Steve Knowles, Stephen Knowles, MD, MRCP
Chief Medical Officer
Halozyme Therapeutics

Annette Williams, MBA, RPh
Vice President, Pharmacovigilance
IQVIA

PROGRAM COMMITTEE

Mariette Boerstoel-Streefland, MD, MBA, MS
Senior Vice Patient Safety, Chief Safety Officer
AstraZeneca

Jim Buchanan, PharmD
President
Covilance LLC

Cheryl Campbell, MS
Associate Director of Executive Operations/
Outreach and Communications
OSE, CDER FDA

E. Stewart Geary, MD
Senior Vice President and CMO
Eisai Co., Ltd., Japan

Jeremy Jokinen, PhD, MS
Vice President, Epidemiology, Safety Science,
Capabilities and Innovation
Bristol-Myers Squibb Company

Jamie Klucken, PharmD, MBA, RPh
FDA/CDER/OSE/Division of Pharmacovigilance
FDA

Linda Scarazinni, MD, RPh
Vice President, Pharmacovigilance & Patient Safety
Abbvie

Annette Stemhagen, DrPH, FISPE
Senior Vice President and Chief Scientific Officer
UBC

Sarah Vaughan
Pharmacovigilance Information Unit Systems
Manager, Medicines and Healthcare products
Regulatory Agency (MHRA), United Kingdom

Jo Wyeth, PharmD
Associate Director for Postmarket Assessments
OMEPRM, OSE, CDER, FDA

Who Should Attend?

Professionals with intermediate to advanced knowledge of, and experience in, clinical safety and who are involved in:

- Drug Safety/Pharmacovigilance
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Benefit-risk assessment and communication
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Research
- Pharmacoepidemiology
- Post-market studies and Real-World Evidence generation
- Customer Engagement Programs, including Patient Support Programs
- Medical Information, Medical Communications
- Health Outcomes

It is designed for professionals who work in the settings of:

- Industry: pharmaceuticals, biologics, combination products, devices
- Clinical Research Organizations, Contract Service Organizations
- Academic Research Centers
- Regulatory Agencies
- Government research programs

Members of board, C-level, Senior Vice Presidents, Vice Presidents, Directors and Heads of departments from pharmaceutical involved in:

- Drug Safety
- Pharmacovigilance
- Risk Management
- Clinical Safety
- Data management and data mining
- Safety & Risk Management
- Signal Detection
- Benefit-Risk Assessment
- Safety Evaluation
- Regulatory Affairs, Pharmacovigilance
- PV Governance
- Safety Surveillance
- Pharmacovigilance Operations
- PV Inspection and Audit Readiness
- Patient Support Programs
- Market Research Programs
- Medical Safety
- Medical Information
- Pharmacoepidemiology

SHORT COURSE DAY ONE | MONDAY, JANUARY 10

10:00AM-1:00PM	**Short Course 1:** Reference Safety Information

SHORT COURSE DAY TWO | WEDNESDAY, JANUARY 12

10:00AM-1:00PM	**Short Course 2:** Aggregate Safety Assessments

SHORT COURSE | FRIDAY, JANUARY 14

10:00AM-1:00PM	**Short Course 3**: Getting Real about Inspections

DAY ONE | MONDAY, JANUARY 24

9:00-10:00AM	**Session 1:** Welcome and Opening Remarks and Keynote: Understanding and Combatting COVID-19 Misinformation
10:00-10:30AM	Break/Visit Virtual Exhibit Hall
10:30-11:30AM	**Session 2:** Effective Risk Communications in the COVID Era
11:30AM-12:30PM	Break/Visit Virtual Exhibit Hall
12:30-2:00PM	**Session 3:** Vaccine Safety Management
2:00-2:30PM	Break/Visit Virtual Exhibit Hall
2:30-4:00PM	**Session 4:** FDA Updates in Pharmacovigilance

DAY TWO | TUESDAY, JANUARY 25

9:00-10:00AM	**Session 5:** Asia & LATAM Updates
10:00-10:30AM	Break/Visit Virtual Exhibit Hall
10:30-11:30AM	**Session 6:** Regulatory Updates from the UK & EU
11:30AM-12:30PM	Break/Visit Virtual Exhibit Hall
12:30-1:30PM	**Session 7:** AI and PV – Current Implementations and Future Directions
1:30-2:00PM	Break/Visit Virtual Exhibit Hall
2:00-3:00PM	**Session 8:** Safety Signaling and Evaluation: Practical Considerations and Tools

DAY THREE | WEDNESDAY, JANUARY 26

9:00-9:15AM	DIA Global PV Roadmap and Intro to PV Track for GAM
9:15-10:15AM	**Session 9:** Planning a Trial with Safety in Mind
10:15-11:00AM	Break/Visit Virtual Exhibit Hall
10:15-11:00AM	Exhibitor Event/Non-CE: Case Study Spotlight
11:00AM-12:00PM	**Session 10:** Post approval Safety Studies: Approaches to Assessing Medication Exposure and Potential Safety Risks during Pregnancy
11:45-12:45PM	Break/Visit Virtual Exhibit Hall
12:45-1:45PM	**Session 11:** Managing Drug Risks – Regulatory Updates and Industry Perspectives
1:45-2:00PM	Closing Remarks

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Describe the requirements for the use, management, and documentation of the reference safety information (RSI) in clinical trials and how they are enforced by regulatory agencies
- Identify the key descriptive and analytical statistics, their use in interpreting measures of risk, and how estimands can be applied to safety analyses
- Analyze, implement, and influence pharmacovigilance inspection preparedness
- Discuss the factors which predict susceptibility to believe misinformation and identify potential interventions to reduce the sharing of misinformation
- Outline the key principles and skills necessary for an effective communication strategy
- Examine the complexities in management of sudden peaks and unprecedented volume of adverse events, discover solutions to deal with sudden peaks in volumes
- Discuss current-state and potential future applications of AI in PV as well as the regulatory challenges and implications
- Recognize challenges and opportunities that occur in prospective pregnancy registries and bring to understanding drug safety during pregnancy
- Integrate RMP and REMS regulatory update information into work practices

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 19.75 contact hours or 1.975 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, FEBRUARY 25, 2022

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. **All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity**. If ACPE credit is not requested by **Friday, February 25, 2022**, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**.

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .9 CEUs for this program.

Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

***IACET CEUs are only available for Short Courses.**

As an Accredited Provider by the Accreditation Council for Pharmacy Education (ACPE) the American Nurses Credentialing Center (ANCC) recognizes ACPE Credit(s)™ issued by DIA as acceptable toward license Nurses Credentialing Center (ANCC) recognizes ACPE Credit(s)™ issued by DIA as acceptable toward license CE requirements for nursing. Please refer to page five in the **requirements** for additional information.

Continuing Education Credit Allocation

January 10, 2022 - Short Course #1 Reference Safety Information: 2.75 contact hours or .275 CEUs, Type of Activity: Knowledge, 0286-0000-22-001-L04-P; IACET: .3 CEUs

January 12, 2022 - Short Course #2 Aggregate Safety Assessments: 2.75 contact hours or .275 CEUs, Type of Activity: Knowledge, 0286-0000-22-002-L04-P; IACET: .3 CEU

January 14, 2022 - Short Course #3 Getting Real About Inspections: 2.75 contact hours or .275 CEUs, Type of Activity: Knowledge, 0286-0000-22-003-L04-P; IACET: .3 CEUs

January 24, 2021 – Pharmacovigilance and Risk Management Strategies Conference – Day 1
4.5 contact hours or .45 CEUs, Type of Activity: Knowledge, 0286-0000-22-004-L04-P

January 25, 2021 – Pharmacovigilance and Risk Management Strategies Conference – Day 2
4 contact hours or .4 CEUs, Type of Activity: Knowledge, 0286-0000-22-005-L04-P

January 26, 2021 – Pharmacovigilance and Risk Management Strategies Conference – Day 3
3 contact hours or .3 CEUs, Type of Activity: Knowledge, 0286-0000-22-006-L04-P

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend the short course and/or individual days of the conference, in their entirety, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, February 9, 2022**.

If you are claiming ACPE credit for this event you must

1. Attend the entire live virtual short course and/or one or both days of the conference
2. Complete a Verification of Attendance Form
3. Send back to **CE@DIAglobal.org** by **February 25, 2022**
4. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Wednesday, February 9, 2022**.

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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SHORT COURSE | MONDAY, JANUARY 10

These sessions are in ET

10:00AM-1:00PM

Short Course 1: Reference Safety Information

Short Courses require an additional registration fee. You do not need to be registered for the forum to attend

Session Chairs
Stephen Knowles, MD, MRCP, Chief Medical Officer, Halozyme Therapeutics

The implementation of the EU requirements for the use of Reference Safety Information (RSI) in determining expectedness of "suspected" serious adverse reactions (SARs) from clinical trials continues to be challenging. This half-day short course will be conducted in two parts. The first part will focus, at a high level, on the basic aspects of the EU Regulation and EU Guidance (including Q&A Documents) that govern the content, placement, use, and management of the Reference Safety Information and compare/contrast with the US FDA approach to assessing expectedness and causality to determine reportability of individual clinical trial cases. The second part will focus on practical aspects of implementing the regulations and guidance, criteria for updating the RSI, UK MHRA approach following Brexit and a review of acceptable and non-acceptable examples of the RSI.

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

- Describe the requirements for the use and management of the RSI in clinical trials
- Determine how the requirements for RSI are enforced by regulatory agencies
- Develop compliant RSI processes and documentation

Instructors
Krisztina L. Debreczeni, MD, Group Medical Director, Medical Review of Single Cases, PV, Bristol-Myers Squibb Co

Ken Lipetz, PhD, MBA, HCLD, Associate Director – Pharmacovigilance Operations, Project Management, Moderna

SHORT COURSE | WEDNESDAY, JANUARY 12

10:00AM-1:00PM

Short Course 2: Aggregate Safety Assessments

Short Courses require an additional registration fee. You do not need to be registered for the forum to attend

Session Chair
Jim Buchanan, PharmD, President, Covilance LLC

This (mainly) formula-free half-day course will introduce a systematic approach for evaluating and assessing adverse events and other safety information, guided by medical judgment, which enables investigators to develop clinical as well as statistical understanding of the safety profile.

Topics to be covered include:

- Denominators and numerators, variability, confidence intervals, p-values, and significance
- Absolute risk, risk ratios, odds ratios, and hazard ratios – when, why, and what to look for
- Safety estimands
- Common abuses of statistics in PV
- Quantitative frameworks for measuring evidence of association
- A multidisciplinary approach that incorporates quantitative methods with clinical judgment
- Scientific evaluation of accumulating program-level safety information throughout drug development

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

- Identify denominators and numerators, variability, confidence intervals, p-values, and significance
- Describe how to interpret measures of risk: risk ratios, odds ratios, and hazard ratios – when, why, and what to look for
- Describe how the new concept of estimands can be applied to safety analyses
- Recognize common abuses of statistics in PV
- Compare accumulating safety data combined across multiple studies
- Evaluate the scientific expertise and medical judgment of multidisciplinary teams
- Develop and communicate the safety story

Instructors

Aggregate Safety Assessments – A Clinical Perspective
Jim Buchanan, PharmD, President, Covilance LLC

Aggregate Safety Assessments – A Statistical Perspective
Greg Ball, PhD, Senior Principal Statistician, Merk & Co

SHORT COURSE | FRIDAY, JANUARY 14 VIRTUAL

10:00AM-1:00PM

Short Course 3: Getting Real about Inspections

Session Chair
Linda Scarazinni, MD, Vice President, Pharmacovigilance & Patient Safety, Abbvie

Regulatory inspections assessing marketing authorisation holder compliance with pharmacovigilance legislation are not new. So why do inspections often seem like a marathon, with crowds of people and a race to the finish line? Organisations strive to be perpetually "inspection ready" but this is often not reflected in the inspection experience.

How might we create a world where inspections are "non-events", where our perpetual proper prior planning prevents poor performance and inspection findings become a thing of the past?

If you're going to run a marathon you don't just prepare for the week beforehand.... Regulatory inspections require investment, poor outcomes can have significant implications, so why run the risk of failing to prepare.

This short session aims to provoke thinking and provide participants with tools and strategies to develop a robust state of inspection readiness, including:

- Strategies that can be built into day-to-day processes to enable an always-inspection-ready mindset
- Frameworks for proactive compliance oversight,
  - Pragmatic risk-taking in PV policy decisions and process design
  - Pre-emptive documentation of decisions and associated rationale,
  - Routine front-room preparedness,
- Knowing when and how to respectful challenge inspection findings
- Developing pragmatic and right-sized CAPA plans to resolve identified non-compliance without over committing or gold-plating compliance

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

- Analyse the maturity of their company's pharmacovigilance inspection preparedness
- Implement tools and strategies to establish a proactive state of inspection readiness
- Identify cross-functional stakeholders in pragmatic resourcing and responses to inspections

Instructors
Carrie Scott, BSc, Director, Safety Compliance, Abbvie, Portugal

Nusrat Sultani, BSc, Associate Director, Safety Compliance

Rebecca Webb, BSc, PgC, Director, Pharmacovigilance Quality Assurance, Abbvie, United Kingdom

Patrick Spracklin, BSc, Senior Director, PV Process, Technology, Data and Innovation, Abbive

DAY ONE | MONDAY, JANUARY 24

9:00-10:00AM

Session 1: Welcome and Opening Remarks and Keynote: Understanding and Combatting COVID-19 Misinformation

Session Chair
Stephen Knowles, MD, MRCP, Chief Medical Officer, Halozyme Therapeutics

This will discuss the Rand lab's research agenda on COVID-19 misinformation (for papers, see **https://bit.ly/3EAmr6K**). Dr. Rand will describe the results of a large-scale study conducted in 16 countries and examine factors that predict susceptibility to belief in COVID-19 misinformation, as well as interventions to identify misinformation at scale and to reduce the sharing of COVID-19 misinformation on social media. Dr. Rand will also describe research (https://bit.ly/3CDVVsi) showing the power of communications from cultural elites for shaping laypeople's attitudes towards COVID-19 vaccination.

Speaker
David Rand, PhD, Erwin H. Schell Professorship & Professor of Management Science, Sloan School, Massachusetts Institute of Technology

10:00-10:30AM **Break/Visit Virtual Exhibit Hall**

10:30-11:30AM

Session 2: Effective Risk Communications in the COVID Era

Session Chairs
Annette Williams, MBA, RPh, Vice President, Pharmacovigilance, IQVIA

Session Description
The COVID Era has resulted in unprecedented levels and types of health communications directed at health care professionals, patients, and the public. This session will first examine challenges from the pandemic. Then, we will review key principles in developing effective communications and will explore methods for effectively engaging communities in discussions about vaccines, therapeutics, and uncertainty. How to overcome communication barriers and ensure individuals can make informed decisions regarding optimal health for themselves, their families, and the larger community.

Speakers
Sandra Quinn, MEd, PhD, Chair, Family Science and Senior Associate Director, Maryland Center for Health University of Maryland School of Public Health

Michele Andrasik, PhD, Director, Social & Behavioral Sciences and Community Engagement, Fred Hutchinson Cancer Research Center

11:30AM-12:30PM **Break/Visit Virtual Exhibit Hall**

12:30-2:00PM

Session 3: Vaccine Safety Management

Session Chair
Mariette Boerstoel-Streefland, MD, MBA, MS, Senior Vice President Global Drug Safety, Alexion Pharmaceuticals, Inc.

Hear from relevant representatives about challenges and learnings of safety management for the unprecendented situation with the vast COVID-19 vaccine rollout in this panel discussion.

Representatives from the primary vaccine producers will provide a short introduction on their experience, covering various angles:

- Pharmacovigilance Operations –handling large amounts of data, safety database management, case entry
- Signal detection and risk communication – 'needle in a haystack'
- Regulatory interactions

The presentations will be followed by a panel discussion where the audience is encouraged pose their questions to gain additional insights from the experts.

Speakers
George Pajovich, RPh, Vice President, Head of Safety Quality and Risk Management, Pfizer Inc

Magnus Nord, MD, PhD, Vice President, Global Patient Safety at AstraZeneca, Sweeden

Marianne Hamilton Lopez, PhD, MPA, Research Director, Value-Based Payment Reform, Duke-Margolis Center for Health Policy

Narayan Nair, Division Director, Division of Epidemiology, CBER FDA

Walter Straus, Vice President, Safety & Pharmacovigilance, Moderna

2:00-2:30PM **Break/Visit Virtual Exhibit Hall**

2:30-4:00PM **Session 4:** FDA Updates in Pharmacovigilance

Session Co-Chairs
Cheryl Campbell, MS, Associate Director of Executive Operations/Outreach and Communications, OSE, CDER, FDA, United States

Jamie Ridley Klucken, PharmD, MBA, RPh, Health Scientist, Division of Pharmacovigilance, OSE, CDER FDA

FDA representatives will provide updates from the Office of Surveillance and Epidemiology (OSE) within CDER, updates on safety surveillance from the Office of Generic Drugs, and updates on Surveillance, Epidemiology, and Risk Management approaches for biologics from CBER.

The 2022 Update on CDER Activities
Gerald Dal Pan, MD, MHS, Director, Office of Surveillance and Epidemiology/CDER, FDA

Updates and Opportunities for Generic Drug Postmarketing Surveillance
Howard Chazin, MD, MBA, Director, Clinical Safety Surveillance Staff, Office of Generic Drugs/CDER, FDA

An FDA-CBER Update on Surveillance, Epidemiology and Risk Management Approaches for COVID-19 Vaccines
Steven Anderson, PhD, Director, Office of Biostatistics and Epidemiology, CBER, FDA

DAY TWO | TUESDAY, JANUARY 25

9:00-10:00AM **Session 5:** Asia & LATAM Updates

Session Chair
E. Stewart Geary, MD, Senior Vice President and CMO, Eisai Co., Ltd., Japan

The session will provide an update on new developments in pharmacovigilance and risk management in Latin America and Asia. The focus will be on providing a broad outline of PV regulations especially where they deviate from ICH standards and recent developments or changes in these countries. Topics of special interest this year include the implementation of GVP in China and rollout of electronic package inserts in Japan.

Pharmacovigilance in China
Vera Liang, MD, Director and Global Safety Risk Lead, Safety Surveillance and Risk Management, Pfizer (China) R&D Co., Ltd., China

Current Status and Recent Developments in Pharmacovigilance in Japan
Makoto Miyazaki, MSc, Medical/Data Science, Safety Risk Management, Pharmacovigilance, Japan Developme, MSD K.K., Japan

LATAM Safety Landscape and Regulatory Updates
Julio Guy Ciolfi Pinto, MD, MBA, Director, Regional Safety Excellence LATAM, Alexion, Astrazeneca Rare Disease, Brazil

10:00AM-10:30AM **Break/Visit Virtual Exhibit Hall**

10:30- 11:30AM **Session 6:** Regulatory Updates from the UK & EU

Session Chair
Sarah Vaughan, Pharmacovigilance Information Unit Systems Manager, Medicines and Healthcare products, Regulatory Agency (MHRA), United Kingdom

This session will provide pharmacovigilance updates from the UK's Medicines & Healthcare products Regulatory Agency and the European Medicines Agency. The landscape for pharmacovigilance and medicine regulation is rapidly evolving and a multifaceted approach to safety monitoring is required to meet challenges such as scientific innovation, greater demands on the healthcare system from aging populations and polypharmacy and increasing data volumes. The two speakers will share their current and upcoming work priorities and key challenges for the Regulatory Agencies in pharmacovigilance and risk management for 2022 and beyond.

Speakers
Sarah Vaughan, Pharmacovigilance Information Unit Systems Manager, Medicines and Healthcare products, Regulatory Agency (MHRA), United Kingdom

Georgy Genov, MD, Head of Pharmacovigilance Office, Quality and Safety of Medicines Department, European Medicines Agency, Netherlands

11:30AM-12:30PM **Break/Visit Virtual Exhibit Hall**

12:30-1:30PM **Session 7:** AI and PV – Current Implementations and Future Directions

Session Chair
Jamie Portnoff, Partner, Founder, Truliant Consulting

Co-Chair
Jeremy Jokinen, PhD, MS, Vice President, Epidemiology, Safety Science, Capabilities and Innovation, Bristol-Myers Squibb Company, United States

This session will examine current uses of artificial intelligence (AI) across the industry and look at future opportunities to leverage AI from an industry and regulatory perspective. Discussions will include both analytic tools and platforms, like multitenant safety databases, which are key enablers to leveraging future-state tools across the industry.

Speakers

Current Implementations of AI and Lessons Learned from COVID-19
Patrick Caubel, MD, PhD, MBA, Chief Safety Officer, Pfizer

Multitenant Solutions to Enable Future Analytics Solutions
Speaker Representative Invited, Bristol Myers Squibb, United Kingdom

Martin Holm-Petersen, Chief Executive Officer, Insife Inc

1:30-2:00PM **Break/Visit Virtual Exhibit Hall**

2:00-3:00PM

Session 8: Safety Signaling and Evaluation: Practical Considerations and Tools

Session Chair
Jim Buchanan, PharmD, President, Covilance LLC, United States

Although the term "safety signal" is commonly used, it can be subject to misunderstanding. Safety evaluation encompasses a wide variety of data sources; thus a signal can take many forms. Large amounts of data can be difficult to review; however, data visualization tools can greatly facilitate the process. Having identified a signal, potential sources of confounding and bias need to be considered. There are various approaches to considering evidence supportive of a causal association which collectively can be organized in a framework such as the Hills Criteria of Causation.

Speakers
Jim Buchanan, PharmD, President, Covilance LLC, United States

Mengchun Li, MD, MPA, Director, Pharmacovigilance, Global Alliance For TB Drug Development

DAY THREE | WEDNESDAY, JANUARY 26

9:00-9:15AM

DIA Global PV Roadmap and Intro to PV Track for GAM

Session Chair
Elena Popa, MPharm, Senior Manager, Scientific Programs, Drug Information Association (DIA), Switzerland

9:15-10:15AM

Session 9: Planning a Trial with Safety in Mind

Session Chair
Jim Buchanan, PharmD, President, Covilance LLC

Understanding the safety profile of an investigational drug is best accomplished when there is safety planning to ensure data collection will answer key questions from health authorities, prescribers, and patients. Such a plan will ensure a consistent approach to collection and analysis of safety data, describe approaches to ongoing aggregate data analysis and identify knowledge gaps to be addressed in post-marketing safety surveillance or studies. A proposed tool is the Aggregate Safety Assessment Plan, which is a modular, multidisciplinary approach to safety planning.

Speakers
Barbara Hendrickson, MD, Immunology Therapeutic Area Head, Pharmacovigilance and Patient Safety AbbVie, Inc.

Lothar Tremmel, PhD, Vice President, Quantitative Clinical Sciences and Reporting, CSL Behring

10:15-11:00AM

Break/Visit Virtual Exhibit Hall

10:15- 11:00AM

Exhibitor Event/Non-CE: Case Study Spotlight

11:00AM-12:00PM

Session 10: Post Approval Safety Studies: Approaches to Assessing Medication Exposure and Potential Safety Risks During Pregnancy

Session Chair
Annette Stemhagen, DrPH, FISPE, Senior Vice President and Chief Scientific Officer, UBC

Chelsea O'Connell, Director, Global Regulatory and R&D Policy, Amgen

Historically, regulators have required sponsors to collect pregnancy safety information in the post-marketing setting through prospective registries. However, pregnancy registries have practical barriers to enrolling subjects and often suffer from the lack of an adequate control group, inadequate power to achieve study objectives, high operational cost, a lack of generalizability, and long timelines before results are available to support clinical decisions.

There is increasing opportunity and ability for real-world data and real-world evidence (RWD/E) from claims and electronic health record (EHR) databases to address some of the challenges seen with registries and more efficiently answer the question of drug safety during pregnancy. Retrospective database studies allow for observation of patients representing a broad population – not just those self-selected for registry enrollment or referred by providers, and the larger sample size enables faster accumulation of data and ultimately insight into patient safety.

This session will discuss various fit-for-purpose pregnancy study options to inform a framework that includes prospective registries, retrospective database studies, and single-arm safety/enhanced pharmacovigilance studies with criteria dependent on the patient population in scope.

Speakers
Representative Invited, OND, CDER, FDA

Carrie Nielson, PhD, MPH, Observational Research Senior Manager, Amgen

Carla Jonker, EMA, South Africa

12:00-12:45PM **Break/Visit Virtual Exhibit Hall**

12:45-1:45PM **Session 11:** Managing Drug Risks – Regulatory Updates and Industry Perspectives

Session Co-Chair
Annette Stemhagen, DrPH, FISPE, Senior Vice President and Chief Scientific Officer, UBC

Jo Wyeth, PharmD, Associate Director for Postmarket Assessments, OMEPRM, OSE, CDER, FDA

Identifying and managing risks is fundamental to ensure safe and effective use of drug products. Approaches for Risk Management Plans (RMP) and Risk Evaluation and Mitigation Strategies (REMS) may evolve over time based on novel drug products entering the market, technology advances, and availability of new safety information. In this session, industry representatives will join with FDA and EMA to provide regulatory updates, address frequently asked questions, and share perspectives on the future direction for RMPs and REMS.

Speaker
Cynthia LaCivita, PharmD, Director, Division of Risk Management, OSE, CDER, FDA

Viola Macolic Sarinic, DrSc, MD, MSc, PRAC Scientific Lead, European Medicines Agency, Netherlands

1:45-2:00PM **Closing Remarks**

Pharmacovigilance and Risk Management Strategies Conference Sponsored Events

Separate RSVP is required for each event. These sponsored sessions are open to all, including those not registered for the full conference. These sponsored sessions are separate to the conference content included in registration. Upon completion of your RSVP a login link will be sent to you for the session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services.

EXHIBITOR EVENT | WEDNESDAY, JANUARY 26

These sessions are in ET

10:15-11:00AM

Exhibitor Event/Non-CE: Case Study Spotlight hosted by IQVIA

80/20 – Getting 80% of Safety Work Done at the Ingestion Step

AI Technology in Safety that can help you change the way you work. Some examples such as below will be covered. Also a discussion on what to look for, what the limits are and what to be aware of. We will provide some case study examples of the results.

Featured Topics

- AE detection in Voice Calls
- NLP Event and Product Identifcation
- OCR Data Extraction
- NLP Coding
- Auto-translation

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Separate RSVP is required.

https://engage.diaglobal.org/IQVIACaseStudySpotlight-PV22_LP.html

Click here to RSVP.