DIA

Pharmacovigilance and Risk Management Strategies Conference

Short Courses: January 19-22, 25 | Conference: January 26-28 | Virtual

Overview

Monitoring of the safety of medicines has always been a top priority for life science companies, regulators, healthcare providers, and patients. The COVID-19 pandemic has created numerous challenges across the healthcare landscape, from patient access to care and the conduct of clinical trials, to data collection for clinical safety and post-market pharmacovigilance, to the need to adapt regulatory expectations to sustain critical care and research while protecting patients and the public.

For pharmacovigilance professionals, the complexity of safety and pharmacovigilance efforts is heightened by the rapid development of multiple vaccines and treatments, the emergent nature of knowledge about the etiology of the corona virus disease, and pervasive misinformation about prevention and treatment practices. The current challenges are ongoing and will have lasting impact on safety, pharmacovigilance, and risk management.

DIA's *Pharmacovigilance and Risk Management Strategies Conference* provides the foundation for strong strategic planning and practical decision-making in pharmacovigilance programs. Developed by recognized experts from the biopharmaceutical industry and global regulatory agencies, this conference provides the background, context, and opportunities to discuss current challenges and to problem-solve around issues that matter most to professionals working in the field.

For this year's program, stakeholders from medicines research, global regulation, and healthcare will join together to analyze the challenges for safety and pharmacovigilance efforts in this uncertain environment and examine effective strategies for addressing gaps and needs. New approaches and collaborations that build on the foundation of sound pharmacovigilance principles to optimize safety and pharmacovigilance practice and ensure safe medicines for patients will be explored.

PROGRAM ADVISORS

Stella Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Access and Risk Management
IQVIA, United Kingdom

William Gregory, PhD
Senior Director, Worldwide Medical and Safety
Pfizer Inc

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PROGRAM COMMITTEE

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Vice President, Pharmacovigilance
IQVIA

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

Schedule-At-A-Glance

SHORT COURSE | TUESDAY, JANUARY 19

10:00AM-1:30PM	**Short Course 1:** Reference Safety Information

SHORT COURSE | WEDNESDAY, JANUARY 20

10:00AM-12:00PM	**Short Course 2:** Pharmacovigilance and Risk Management Planning Part 1

SHORT COURSE | THURSDAY, JANUARY 21

10:00AM-1:45PM	**Short Course 2:** Pharmacovigilance and Risk Management Planning Part 2

SHORT COURSE | FRIDAY, JANUARY 22

10:00AM-1:45PM	**Short Course 2:** Pharmacovigilance and Risk Management Planning Part 3

SHORT COURSES | MONDAY, JANUARY 25

10:00AM-1:30PM	**Short Course 3:** Introduction to Statistics in Pharmacovigilance

DAY ONE | TUESDAY, JANUARY 26

9:45-11:00AM	**Welcome and Session 1:** Keynote Address: Trustworthy Communication of Statistics and Risk in the Age of COVID-19
11:00-11:30AM	Networking Break
11:00-11:30AM	Exhibit Event/Non-CE: Coffee Corner
11:30AM-12:30PM	**Session 2:** Design and Conduct of COVID-19 Protocols – Implications for Efficacy and Safety
12:30-1:00PM	Networking Break
1:00-2:00PM	**Session 3:** Adapting Safety Data Collection and Management in Clinical Trials During a Pandemic – Potential Implications and Lessons Learned from COVID-19
2:00-2:30PM	Networking Break
2:30-3:30PM	**Session 4:** Assessing the Impact of COVID and Implications for Pharmacovigilance in the Future
4:30-5:30PM	DIA 2021 Exclusive

DAY TWO | WEDNESDAY, JANUARY 27

10:00-11:00AM	**Session 5:** FDA Updates in Pharmacovigilance
11:00-11:30AM	Networking Break
11:30AM-12:30PM	**Session 6:** Asia and Latin America Region Updates
12:30-1:30PM	Networking Break
1:30-3:00PM	**Session 7:** Artificial Intelligence and Natural Language Processing: Offering True Benefits to PV Organizations Today
3:00-3:30PM	Networking Break
3:30-4:30PM	**Session 8:** REMS and RMP Effectiveness Evaluation: Industry and Regulatory Perspectives
4:45-5:30PM	Sponsored/Non-CE Roundtable Sessions

DAY THREE | THURSDAY, JANUARY 28

8:45-9:30AM	Sponsored/ Non-CE Roundtable Sessions
9:30-10:00AM	**Session 9:** Signaling in EudraVigilance - Where are We?
10:00-10:15AM	Networking Break
10:15-11:15AM	**Session 10:** European Regulatory Updates
11:15AM-12:00PM	Networking Break
12:00-1:00PM	**Session 11:** How not to Drown in Data – Can ICH Move us Forward?
1:00-1:30PM	Networking Break
1:30-2:30PM	**Session 12:** Pharmacovigilance Approaches for Drug-Device Combination Products

Learning Objectives

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

- Describe the impact of innovative designs, rapidly moving development programs, and early authorizations for COVID-19 therapies and vaccines on safety monitoring, safety endpoints, and ongoing signal detection and risk management activities for these products
- Identify options for addressing potential data "gaps" caused by changes to routine data collection in response to the pandemic situation
- Identify approaches for measuring the effectiveness of risk management plans (RMPs) and risk evaluations and mitigation strategies (REMS)
- Discuss the regulatory landscape of safety surveillance for drug products including generics and biologics, including regulatory requirements related to COVID data collection and their wider impact on on post-marketing surveillance
- Describe the current landscape for pharmacovigilance regulation in Europe, including the upcoming work priorities for MHRA & EMA
- Gain awareness of potential issues for PV compliance and country-specific expectations for the conduct of pharmacovigilance in the Asia and Latin America regions and how they can be addressed
- Examine emerging strategies and tools for managing increasing volumes of safety-related data from multiple and new sources

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 28.5 contact hours or 2.85 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, MARCH 5, 2021

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, March 5, 2021, 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 1.8 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.

Nursing

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 CE requirements for nursing. Please refer to the following link for additional information:
http://www.nursecredentialing.org/Certification/CertificationRenewal/RenewalFAQs

Credit Allocation

Short Course 1: Reference Safety Information: 3.5 contact hours or .35 CEUs, Type of Activity: Knowledge, 0286-0000-21-001-L04-P; IACET: .4 CEUs

Short Course 2: Pharmacovigilance and Risk Management Planning Parts 1-3: 9.5 contact hours or .95 CEUs, Type of Activity: Knowledge, 0286-0000-21-002-L04-P; IACET: 1 CEU

Short Course 3: Introduction to Statistics in Pharmacovigilance: 3.5 contact hours or .35 CEUs, Type of Activity: Knowledge, 0286-0000-21-003-L04-P; IACET: .4 CEUs

Conference Day 1: 4 contact hours or .4 CEUs, Type of Activity: Knowledge, 0286-0000-21-005-L04-P

Conference Day 2: 4.5 contact hours or .45 CEUs, Type of Activity: Knowledge, 0286-0000-21-006-L04-P

Conference Day 3: 3. 5 contact hours or .35 CEUs, Type of Activity: Knowledge, 0286-0000-21-007-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 **Thursday, February 11, 2021**.

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 4, 2021**
4. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Thursday, February 11, 2021**.

DIA Disclosure Policy

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

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Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

SHORT COURSE | TUESDAY, JANUARY 19

10:00AM-1:30PM

Short Course 1: Reference Safety Information

Krisztina Debreczeni, MD, Head, Medical Safety Review and Expedited Safety Reporting, Worldwide Patient Safety, Bristol-Myers Squibb Co.

Kenneth Lipetz, MD, PhD, MBA, MSc, GPS Medical Business Advisor, Eli Lilly and Company

Stephen Knowles, MD, MRCP, Chief Medical Officer, Drug Safety and Pharmacovigilance, 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 short course, participants should be able to:

- Describe the requirements for the use and management of the RSI in clinical trials
- Understand how the requirements for RSI are enforced by regulatory agencies
- Be able to develop compliant RSI processes and documentation

SHORT COURSE | WEDNESDAY, JANUARY 20 – SHORT COURSE 2

Stella Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP, Vice President, Global Head of Early Access and Risk Management, IQVIA, United Kingdom

William Gregory, PhD, Senior Director, Safety and Risk Management, Pfizer Inc

Anne Ambrose, MPharm, MSc, RPh, RAC, Chairperson of the CMDh EU PSUR work sharing working party, Medicines & Healthcare Products Regulatory Agency, United Kingdom

This full-day short course will be spread over three days and will focus on basic aspects of the regulatory framework for pharmacovigilance in the context of risk management planning and on the practical aspects of managing biopharmaceutical product risks in the context of benefits and the health care delivery system. The main focus will be on the EU and US situations, but this will be supplemented with experience gained in other selected jurisdictions.

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

- Discuss similarities and differences in risk management planning in the three ICH regions and other selected jurisdictions
- Describe the differences between important identified risks and important potential risks
- Outline the basic structure and contents of an EU Risk Management Plan (in the context of a Risk Management System) and a Risk Evaluation and Mitigation Strategy (REMS)
- Discuss primary and non-routine tools for managing product risks, how the effectiveness of a selected tool is assessed, and points to consider for the modification, revision, or release of a given non-routine intervention

10:00AM-12:00PM

Short Course 2: Pharmacovigilance and Risk Management Planning Part 1

- Introduction
- Pre-Marketing Data
- Pharmacovigilance Planning
- Q&A

SHORT COURSE | THURSDAY, JANUARY 21

10:00AM-1:45PM

Short Course 2: Pharmacovigilance and Risk Management Planning Part 2

- EU Situation
- How to Meet Current EEA Requirements
- MHRA
- Case Study Exercise
- Q&A

SHORT COURSE | FRIDAY, JANUARY 22

10:00AM-1:45PM

Short Course 2: Pharmacovigilance and Risk Management Planning Part 3

- US Situation
- Rest of World Examples - Situation in Japan, China
- Practical Aspects
- Q&A

SHORT COURSES | MONDAY, JANUARY 25

10:00AM-1:30PM

Short Course 3: Introduction to Statistics in Pharmacovigilance

Lesley Wise, PhD, MSc, Managing Director Wise PV&RM Ltd, United Kingdom

This (mainly) formula-free half day course will provide a basic introduction to statistics and probability which will be applied in the context of drug safety. Topics to be covered include:

- Understanding denominators and numerators
- Measuring and presenting risk
- Comparing risks: introduction to absolute risk, risk ratios, odds ratios, and hazard ratios when, why, and what to look for
- Understanding variability, confidence intervals, p-values, and significance
- Meta-analysis vs. pooled analysis
- Common statistics abuses in PV

At the completion of this activity, the participant should be able to:

- Define and explain the significance of denominators and numerators
- Discuss common approaches to measuring and presenting risk
- Describe standard methods of comparing risks, including absolute risk, risk ratios, odds ratios, and hazard ratios – when, why, and what to look for
- Explain the concepts of variability, confidence intervals, p-values, and significance
- Compare Meta-analysis vs. pooled analysis
- Recognize common statistics abuses in PV

DAY ONE | TUESDAY, JANUARY 26

9:45-11:00AM

Welcome and Session 1: Keynote Address - Trustworthy Communication of Statistics and Risk in the Age of COVID-19

David Spiegelhalter, PhD, Chair of the Winton Centre for Risk and Evidence Communication, Department of Pure Mathematics and Mathematical Statistics, Cambridge University, United Kingdom

11:00-11:30AM **Networking Break**

11:00-11:30AM **Exhibit Event/Non-CE:** Coffee Corner

See Page 16 for more information and instructions on how to RSVP!

11:30AM-12:30PM **Session 2:** Design and Conduct of COVID-19 Protocols – Implications for Efficacy and Safety

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

The COVID-19 global pandemic has necessitated the rapid development, approval and conduct of clinical trials in order to address the urgent public health need for therapeutics and vaccines. The speed at which these programs has progressed is unprecedented. In this session, we will discuss the safety monitoring and safety endpoints in the trials; efficacy endpoints, including details of interim analyses; safety signal detection and risk management activities; Considerations for trial management between EUA/conditional marketing authorization and full approval and the role of the DSMB.

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

- Understand the design of clinical trials to answer the urgent questions of COVID-19 therapeutics and vaccines
- Understand the safety monitoring required for rapidly moving programs
- Understand the implications of early authorizations on ongoing studies and safety monitoring

SARS-CoV-2: From Pandemic Outbreak to Vaccine in 2020
Larry Smith, PhD, Executive Consultant: COVID-19 Vaccine Development

COVID-19 Vaccine Development
Peter Marks, MD, PhD, Director, CBER, FDA

12:30-1:00PM **Networking Break**

1:00-2:00PM **Session 3:** Adapting Safety Data Collection and Management in Clinical Trials During a Pandemic – Potential Implications and Lessons Learned from COVID-19

Session Chair
Lesley Wise, PhD, MSc, Managing Director Wise PV&RM Ltd, United Kingdom

During the COVID-19 pandemic, hospital and clinic resources and personnel have been stretched, and there has been a need to keep clinical trial participants away from environments where they may be at greater risk of exposure to COVID-19. This has implications for safety management (eg scheduled visits and lab assessments) and potentially for efficacy reporting (eg for patients who complete the study but cannot attend for outcome measurements). Regulatory authorities have produced guidance on potential safety amendments, but the implications for the clinical trials finalization, reporting and assessment are unclear. This session will hear from an industry representative outlining the challenges the COVID situation brings for clinical trial management and regulatory authority representative outlining the expectations for protocol amendments.

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

- Understand the need to change clinical trial data collection during public health emergencies
- Understand the need to assess potential long term implications on clinical trial data assessment of changes in clinical trial monitoring/conduct
- Identify options for addressing potential data "gaps" caused by changes to routine data collection

Speakers
Lesley Wise, PhD, MSc, Managing Director Wise PV&RM Ltd, United Kingdom

John Concato, MD, MS, MPH, Associate Director for Real-World Evidence Analytics, Office of Medical Policy, CDER, FDA

COVID-19 Lessons Learned: Challenges (and Opportunities!) in Data Collection and Assessment
Jeremy Jokinen, PhD, MS, Vice President Epidemiology, Safety Science, Capabilities and Innovation Worldwide Patient Safety, Bristol-Myers Squibb Company

2:00-2:30PM **Networking Break**

2:30-3:30PM **Session 4:** Assessing the Impact of COVID and Implications for Pharmacovigilance in the Future

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

During 2020, the COVID-19 pandemic has created numerous challenges and opportunities across the healthcare landscape. Regulatory authorities have provided emerging guidance during the pandemic that has the potential to impact ongoing regulatory expectations. This session will begin with a review of the key challenges experienced and the initial industry response, followed by a regulatory overview of current COVID-related data collection requirements and its impact on post-marketing surveillance. This session will also explore several operational strategies that have proved successful and warrant long-term consideration. Lastly, participants will be invited to engage in a dialogue on the future implications for pharmacovigilance.

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

- Identify the key challenges faced by pharmacovigilance departments while operating during the COVID pandemic
- Describe the relevant regulatory requirements related to COVID data collection and understand their wider impact
- Detail the operational impacts across the three vital pillars (people, process, and technology) of every pharmacovigilance organization and highlight opportunities for future efficiencies

AstraZeneca Vaccine Plan an Extraordinary Opportunity
Vita Petrik, RN, BSN, Senior Director, PV Processes, Partnerships and Contracts, Astrazeneca Pharmaceuticals

A Regulatory Perspective on COVID Data Collection & Its Impact on Post Marketing-surveillance
Kendal Harrison, Pandemics Systems Delivery Manager, Vigilance & Risk Management of Medicines Division, Manager Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

The Operational Realities and Benefits of the COVID Era
Annette Williams, BS Pharmacy, MBA, Vice President, Pharmacovigilance, IQVIA

4:30-5:30PM **DIA 2021 Exclusive**

DIA is hosting a series of content previews around the United States counting down to the *DIA 2021 Global Annual Meeting*, and we're kicking off the series in conjunction with the DIA *Pharmacovigilance and Risk Management Strategies Conference!** Enjoy a complimentary sneak peek and networking with a multidisciplinary group of colleagues who share your passion to drive innovation from the lab to patients. It's an exclusive preview of the exciting content offerings via virtual fireside chat, with an exciting bonus for you.

DAY TWO | WEDNESDAY, JANUARY 27

10:00-11:00AM **Session 5:** FDA Updates in Pharmacovigilance

Session Chair
Gerald Dal Pan, MD, MHS, Director, Office of Surveillance and Epidemiology/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.

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

- Identify advances in pharmacovigilance and risk management strategies
- Examine the FDA assessment of emerging safety signals and review of safety data
- Discuss the regulatory landscape of safety surveillance for drug products including generics and biologics

An Update on CDER Pharmacovigilance and Risk Management Activities
Gerald Dal Pan, MD, MHS, Director, Office of Surveillance and Epidemiology, CDER, FDA

An Update on CBER Biologics Pharmacovigilance and Risk Management Activities
Steven Anderson, PhD, M.P.P., Director, Office of Biostatistics and Epidemiology, CBER, FDA

Update on Safety Surveillance for Generic Drugs
Howard Chazin, MBA, MD, Director, Clinical Safety Surveillance Staff, Office of Generic Drugs, CDER, FDA

11:00-11:30AM **Networking Break**

11:30AM-12:30PM **Session 6:** Asia and Latin America Region Updates

Session Chair
E. Stewart Geary, MD, Senior Vice President, Global Safety Officer, Director, Corporate Medical Affairs HQ Eisai Co., Ltd., Japan

The session will provide an update on new developments in pharmacovigilance and risk management in Latin America and Asia including Japan. 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.

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

- Understand in broad outline the PV regulations in Asia (including Japan) and Latin America
- Learn of the most recent changes in regulations which affect risk management or pharmacovigilance in these countries
- Gain awareness of potential issues for PV compliance and country-specific expectations for the conduct of pharmacovigilance in those regions and how they can be addressed

Pharmacovigilance Update for Latin America
Fernando Pereira, RPh, Director, Regional PV Lead Latin America (PACoE), Abbvie, Brazil

Pharmacovigilance Update for Japan and Asia
Mamiko Kasho (Konishi), Executive Director, Global PV Management Dept., Global Safety HQs, Eisai Co., Ltd.

12:30-1:30PM **Networking Break**

1:30-3:00PM **Session 7:** Artificial Intelligence and Natural Language Processing: Offering True Benefits to PV Organizations Today

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

Lisa Harinstein, PharmD, BCCCP, Team Leader, Division of Pharmacovigilance, OSE, CDER, FDA

Annette Williams, BS, Pharmacy, MBA, Vice President, Pharmacovigilance, IQVIA

Life science companies are actively pursuing automated solutions to address the challenge of managing increasing volumes of safety-related data from a myriad of sources, as well as to help identify, extract and interpret data for improved pharmacovigilance (PV). Assessing technology tools – such as robotic process automation (RPA), and natural language processing (NLP) has become more commonplace. This session will focus on specific use cases across the pharmacovigilance continuum. It will showcase

how AI/NLP is being applied to increase robustness and efficiency for AE case intake from various territories across the globe. We will explore how NLP is now being employed to identify patients at risk in clinical trials as well as develop safety-related intelligence landscapes from scientific literature, internal preclinical and clinical safety reports that can be used to contextualize potential safety signals, as well as how regulatory agencies are utilizing the technology for pharmacovigilance.

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

- Define AI, RPA, and NLP and its application
- Outline how pharma organizations are using NLP for safety applications; including limitations and validation
- What is the current situation; where are various stakeholders in their use of AI
- Understand effective utilization of AI and NLP for intake of AE information from various territories worldwide
- List how the FDA is applying AI to pharmacovigilance strategies.

Global Intake Using NLP, Translation, AI in an Ever-changing PV Organization part 1
Mariette Boerstoel-Streefland, MD, MBA, MS, Senior Vice President Global Drug Safety, Alexion Pharmaceuticals, Inc.

Global Intake Using NLP, Translation, AI in an Ever-changing PV Organization part 2
Francois Audibert, MSc, Vice President US Operations, Vitrana

New Uses of Natural Language Processing (NLP) in Product Safety
Jane Reed, PhD, Director Life Sciences, Linguamatics, an IQVIA Company, United Kingdom

Leveraging Applied AI Within Pharmacovigilance
Oanh Dang, PharmD, BCPS, Regulatory Science and Applied Science, Pharmacovigilance, FDA

Patient Safety Monitoring using NLP and Machine Learning: A Healthcare Perspective
Allan Fong, MS, Research Scientist and Data Scientist, Medstar Health National Center For Human Factors In Healthcare

(Aaron) Zachary Hettinger, MD, MS, Director of Cognitive Informatics, Medstar Health National Center For Human Factors In Healthcare

3:00-3:30PM **Networking Break**

3:30-4:30PM **Session 8:** REMS and RMP Effectiveness Evaluation: Industry and Regulatory Perspectives

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

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

The measurement of the effectiveness of risk management plans (RMPs) and risk evaluation and mitigation strategies (REMS) remains an underdeveloped and underappreciated aspect of bringing a drug to market. This session will discuss various approaches to evaluating the effectiveness of these programs from both industry and regulator perspectives. Opportunities to advance the science of effectiveness measurement will be considered and approaches to incorporate patient-voice will be discussed.

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

- Identify effectiveness measure approaches that can be applied to risk minimization programs
- Identify similarities and differences in effectiveness evaluations between the US and the EU
- Discuss approaches to incorporate patient voice into effectiveness measures

Risk Minimization Program Evaluation: How Can we Advance the Science?
Meredith Smith, DrPH, PhD, MPA, Director, Risk Management, Global Drug Safety, Research and Development, Alexion Pharmaceuticals, Inc.

Speakers
Janine Collins, MD, LLM, Executive Director Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation, Switzerland

Logic Model: A Tool to Bridge REMS Design and Evaluation
Gita Toyserkani, MBA, PharmD, Associate Director for Research & Strategic Initiatives, CDER, FDA

4:45-5:30PM **Exhibit Event/Non-CE:** Sponsored/Non-CE Roundtable Session

DAY THREE | THURSDAY, JANUARY 28

8:45-9:30AM **Exhibit Event/Non-CE:** Sponsored Roundtable Session

See Page 16 for more information and instructions on how to RSVP!

9:30-10:00AM **Session 9:** Signaling in EudraVigilance - Where are We?

Session Chair
Val Simmons, MB, BS, FFPM, Senior Medical Fellow, Global Patient Safety, Eli Lilly and Company, United Kingdom

Under the 2010 Pharmacovigilance Legislation in the EU, the need to conduct signal detection in the Eudravigilance (EV) regulatory database was originally confined to the European Medicines Agency and the Member State Authorities. This situation was amended under the subsequent Implementing Regulation in 2012 to include Marketing Authorisation Holders; a step which led to concerns that this appeared to represent triplication of effort with no ostensible value to public health or patient safety. Following an industry position paper, the GVP guidance for signal management was revised in November 2017 with a 6-month implementation period granted. Importantly a one-year pilot was agreed in June 2017 with EMA and this was limited to the active substances under additional monitoring at the time (288 products), rather than include all products on the EU market at that time. This pilot was subsequently extended to December 2019 and then again to the end of 2021 following discussions with the European Commission. In the interim period, data were collected by multiple companies to assess the effectiveness of EV as an additional signal detection tool over and above existing data courses. This session will discuss the results of the data collected during the pilot, present feedback on the pilot noted by EMA, and highlight subsequent steps that have been agreed through to 2021.

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

- Understand the background, including industry activities in relation to signaling in the Eudravigilance database.
- Learn about the results of industry-based data collection on the effectiveness of Eudravigilance in generating new safety signals.
- Understand the experience of industry- based signaling in EV presented by the EMA
- Learn about the next steps to be taken through to the end of the pilot in 2021.

Signalling in Eudravigilance – Where are we now????
Achint Kumar Gupta, MD, DrMed, EU QPPV - Safety & Benefit-Riak Management, Biogen, United Kingdom

10:00-10:15AM **Networking Break**

10:15AM-11:15PM **Session 10:** European Regulatory Updates

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

This session will provide updates from the UK's Medicines & Healthcare products Regulatory Agency the Danish Medicines Agency and the Netherlands Medicines Evaluation Board. The three speakers will share their current and upcoming work priorities and key challenges for the Regulatory Agencies in pharmacovigilance & risk management for 2021 and beyond.

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

- Understand the current landscape for pharmacovigilance regulation in Europe
- Describe the upcoming work priorities for MHRA, DKMA and MEB in their regulatory roles
- Discuss the challenges and opportunities identified for future pharmacovigilance activities in Europe

Speakers

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

Anja Van Haren, MSc, EudraVigilance Coordinator, Medicines Evaluation Board, Netherlands

11:15AM-12:00PM **Networking Break**

12:00-1:00PM **Session 11:** How not to Drown in Data – Can ICH Move us Forward?

Session Chairs

Val Simmons, MB, BS, FFPM, Senior Medical Fellow, Global Patient Safety,Eli Lilly and Company, United Kingdom

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

For several years, an increasing amount of individual case safety data has been noted from multiple sources, particularly in the post marketing setting. In this respect, more data does not necessarily translate into optimized signal detection and evaluation, particularly when originating from certain data sources, notably patient support programmers. Recent published findings have supported concerns that overwhelming safety databases with less informative data from PSPs may not only create false safety signals but also potentially obscure true safety signals. These findings provided an impetuous to the reopening of ICH E2D (R1) which is currently in Step 1. In a parallel initiative, ICH E19 aims to optimize safety data collection in late stage clinical trials, using a selective approach in order to improve the efficiency of these clinical trials, as well as reduce the burden on study participants. ICH E19 was released for consultation in 2019 and is currently being updated based on this feedback. This session will evaluate the status of both ICH guidelines and discuss their anticipated contribution to optimizing safety data collection from both clinical trial and post marketing settings.

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

- Understand the need to optimize safety data collection requirements from both clinical trial and post marketing settings
- Understand the stimulus for re-opening ICH E2D and current proposals for safety data collection from PSPs
- Learn about the key challenges to developing standards for optimizing safety data collection in a CT setting and how Step 2 consultation feedback is being addressed

Speakers

Vickie Edwards, RPh, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, Inc.

Ellis Unger, MD, Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, OND, FDA

1:00-1:30PM **Networking Break**

1:30-2:30PM

Session 12: Pharmacovigilance Approaches for Drug-Device Combination Products

Session Chair

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

Novel drug-device combination products are expected to continue entering the global marketplace and provide great opportunities for clinical benefit. These types of products also introduce challenges in pharmacovigilance for integrating device and drug product expertise, gathering and coding adverse event, device malfunction, and medication error information, and deciphering possible relationships with the drug, device, or product itself. This session will use a case-based approach to glean perspectives from regulators and industry on assessing reports of suspected device malfunction versus use errors with drug-device combination products.

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

- Describe the role of human factors engineering in designing drug-device combination products with a user interface that supports safe and effective use
- Propose an effective approach for surveilling suspected use errors versus malfunction with drug-device combination products
- Discuss strategies to increase efficiency for gathering, coding, and evaluating postmarket information involving drug-device combination products

Human Factors in Medical Product Design & Development : Post-market Considerations

Jason Flint, MBA, PMP, Human Factors Reviewer, Associate Director for Human Factors, FDA, CDER, Office of Surveillance and Epidemiology (OSE), Office of Medication Error Prevention and Risk Management (OMEPRM), Division of Medication Error Prevention and Analysis (DMEPA)

Combination Product Postmarketing Safety Reporting Requirements Implementation Update

Captain Melissa Burns, MS, Senior Program Manager, Office of Combination Products, OCPP, OC, FDA

Speaker

James Duhig, PhD, Director, Patient Integration, AbbVie, Inc.

Pharmacovigilance and Risk Management Strategies Conference
Exhibitor Sponsored Events

Separate RSVP is required for each event. For more information, or to RSVP, visit **https://pvrms21.us2.pathable.com/networking-events**. All events listed below are not eligible for continuing education (CE).

TUESDAY | JANUARY 26

11:00-11:30AM

Apcer: Transitioning to Digital Risk Minimization - The journey to our new normal.

Presenters

Dr. Jay Dave, BDS, Risk Management Lead

Dr. Vineet Kacker, PhD, Co-Founder, Managing Director, and Global Technical Director

The discussion focuses on the ongoing pandemic situation and its positive impact on Risk Minimization Measures (RMM) awareness. The challenges that need to be considered in the light of regulatory and industry landscape during implementation of Digital RMM. Gain insights on implementing an effective Digital Risk Management system with real world examples supporting possible solutions and the growing role of social media.

WEDNESDAY | JANUARY 27

4:45-5:30PM

Covance: Assessing Safety and Managing the Risks of Vaccine Development at a 'Pandemic Speed'.

Moderator

Jerome Premmereur, MD, Vice President Patient Safety Solutions & Adjudication

Vaccines for COVID-19 are being developed across the world at speeds that have never been previously achieved. With such an extraordinary effort we are bound to encounter challenges from a post-marketing safety monitoring and vaccine safety communication perspective. The vaccine will have to be administered swiftly and effectively across diverse populations that requires robust pharmacovigilance and surveillance systems to be in place to handle the imminent surge in safety reports and supporting data, and to also account for effective vaccine safety communication. The success of this colossal undertaking will require significant investment and collaboration from stakeholders across the globe.

4:45-5:30PM

Genpact: The Next Generation of Pharmacovigilance

Moderator

Eric Sandor, PVAI Business Leader

The pharmacovigilance (PV) landscape is changing rapidly, setting the scene for the next generation of pharmacovigilance, shaped by converging forces from the healthcare, technology, regulatory, and societal domains. From advances in genomics, nanotechnology, and artificial intelligence to the exponential increase in the velocity and volume of data – the demands on PV Organizations in the future will be unprecedented, and all amidst mounting pressures from society for greater transparency.

THURSDAY | JANUARY 28

8:45-9:30PM

Trilogy Writing & Consulting: Patients and PV – is the RMP lay summary enough?

Moderator

Lisa Chamberlain James, PhD, Senior Partner

This roundtable will discuss the problems of writing for patients in general, and specifically when discussing aspects of benefit and risk (for example, part 6 of the RMP and the lay summary of clinical trial results- EU Reg 536/2014). The participants will discuss whether there are other ways to reach patients and if the currently mandated requirements are producing documents that are fit for purpose. Finally, participants will brainstorm ways to improve communication with patients and initiatives to harmonize and help this across the industry.

Earn While You Learn at the 2021 Pharmacovigilance and Risk Management Strategies Conference!

There are several opportunities for you to win prizes while exploring the platform, getting to know our exhibitors, and meeting each other. ***The best part, you can keep the monetary prize or pay it forward!*** If you wish, we will donate to a registered U.S. Charity in your name. You can search **here** for eligible organizations.

Two Opportunities to Win

#1 - Highest Overall Score

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Keep an eye on the leaderboard to see who is on top!

How To Earn Points:

Action	Occurrence	Points
Meet with an Exhibitor	Every time	10 pts
Participate in a group video meeting	Every time	10 pts
Request Info from Exhibitor	Every time	10 pts
Watch exhibitor/sponsor videos	Every time	10 pts
Download exhibitor/sponsor files	Every time	10 pts
Accept private meeting	Every time	10 pts
Request private meeting	Every time	10 pts
Post photo in forum	Only Once	10 pts
Send private message	Only Once	10 pts
Add profile photo	Only Once	10 pts
Watch a webinar	Every time	5 pts
Post message in discussion	Every time	5 pts
Participate in poll	Every time	5 pts

#2 - Attend Exhibit Sponsored Events - $125 e-gift card*

Attend an exhibit sponsored event such as Happy Hour, Coffee Corner, Roundtable, Case Study Spotlight. Note that separate sign-ups are required. Each attendance = 1 entry to win. Winner will be drawn at random. Winner to be notified the week following the conference via email.

Earn points starting January 18th - January 27th

If you have any questions, please contact **Patti Shaughnessy**.

*You can select Amazon, Visa, American Express gift cards

NOTE - Exhibit Staff are not eligible to win prizes. DIA will review leaderboard and award prizes to the top 3 eligible users.