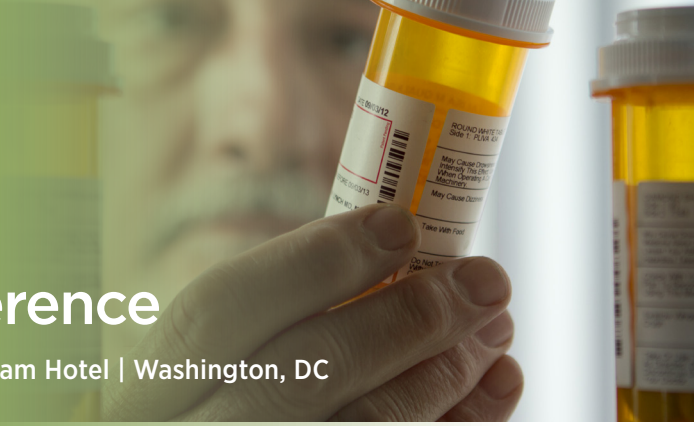
DIA

Pharmacovigilance and Risk Management Strategies Conference

Short Courses: January 21 | Conference: January 22-24 | Omni Shoreham Hotel | Washington, DC



PROGRAM CO-CHAIRS

Stella C. F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management
IQVIA, United Kingdom

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc

PROGRAM COMMITTEE

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UBC, An Express Scripts Company

Lesley Wise, PhD, MSc
Managing Director
Wise Pharmacovigilance and Risk Management Ltd., United Kingdom

Overview

DIA's *Pharmacovigilance and Risk Management Strategies Conference* provides the strongest context, background, updates, new developments, and future direction for regulations and guidance on safety, pharmacovigilance, and risk management strategies that cannot be found in any other meeting. The content of this event is developed by top experts from the biopharmaceutical industry and global regulatory agencies, and DIA will convene the best speakers from around the world to discuss the current challenges and issues that matter most to professionals working in the field.

Highlights

- Global Regulatory Updates
- Daily Keynote Speakers
- Luncheon Round Table Discussions with Key Thought Leaders
- Special Hot Topic Session: Key Hot Topics Examined In-Depth
- Tabletop Exhibits and Networking Opportunities

Who Should Attend

Professionals 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

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.

Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

Schedule At-A-Glance

SHORT COURSES | SUNDAY, JANUARY 21		ROOM
7:30AM-5:00PM	Short Course Registration	West Registration Desk
7:30-8:30AM	Continental Breakfast and Networking	Congressional Foyer
9:00AM-5:00PM	**Short Course 1:** PBRER	Cabinet Room
9:00AM-5:00PM	**Short Course 2:** Pharmacovigilance and Risk Management Planning	Congressional Room
9:00AM-12:30PM	**Short Course 3:** Pharmacovigilance Inspections Part 1: Readiness, Conducting, Findings, and Report-Outs	Forum Room
12:30-1:30PM	Luncheon for Short Course Attendees	Executive Room
1:30-5:00PM	**Short Course 4:** Pharmacovigilance Inspections Part 2: Response, Measurement, Resolution, and Tracking	Forum Room

DAY ONE | MONDAY, JANUARY 22		ROOM
7:00AM-5:30PM	Registration	Ambassador Foyer
7:15-8:15AM	Continental Breakfast, Exhibits, and Networking	Ambassador Ballroom
8:15-8:30AM	**DIA Opening Remarks**	Regency Ballroom
8:30-8:45AM	**Welcome Remarks**	Regency Ballroom
8:45-9:30AM	**Opening Keynote:** Patient Advocacy in Rare Disease: Duchenne Muscular Dystrophy	Regency Ballroom
9:30-11:00AM	**Session 1:** FDA Updates	Regency Ballroom
11:00-11:30AM	Refreshment, Exhibits, and Networking Break	Ambassador Ballroom
11:30AM-12:30PM	**Session 2:** The New ICH	Regency Ballroom
12:30-2:00PM	Luncheon and Round Table Discussions	Ambassador Ballroom
2:00-3:30PM	**Session 3:** Operational Hot Topic: Machine Learning/Artificial Intelligence in Pharmacovigilance	Regency Ballroom
3:30-4:00PM	Refreshment, Exhibits, and Networking Break	Ambassador Ballroom
4:00-5:30PM	**Session 4:** Combination Products	Regency Ballroom
5:30-6:30PM	Networking and Exhibitor Reception	Ambassador Ballroom
6:30-9:30PM	Dine Arounds	

Schedule At-A-Glance

DAY TWO | TUESDAY, JANUARY 23		ROOM
7:30AM-6:00PM	Registration	Ambassador Foyer
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking	Ambassador Ballroom
8:30-8:45AM	**Welcome Remarks Day Two**	Regency Ballroom
8:45-9:30AM	**Day Two Keynote:** Data Rich, Information Poor – Can We Turn Health Records into a Truly Learning Healthcare System?	Regency Ballroom
9:30-11:00AM	**Session 5:** EU Updates	Regency Ballroom
11:00-11:30AM	Refreshment, Exhibits, and Networking Break	Ambassador Ballroom
11:30AM-12:45PM	**Session 6:** Clinical Trial Issues	Regency Ballroom
12:45-2:00PM	Luncheon, Exhibits, and Round Table Discussions	Ambassador Ballroom
2:00-2:45PM	**Mid-Day Keynote**	Regency Ballroom
2:45-4:15PM	**Session 7:** Update on New Treatments	Regency Ballroom
4:15-4:45PM	Refreshment, Exhibits, and Networking Break	Ambassador Ballroom
4:45-6:00PM	**Session 8:** Advanced Therapeutics Pharmacovigilance and Risk Management	Regency Ballroom

DAY THREE | WEDNESDAY, JANUARY 24		ROOM
7:00AM-3:30PM	Registration	Ambassador Foyer
7:00-8:00AM	Continental Breakfast, Exhibits, and Networking	Ambassador Ballroom
8:00-8:15AM	**Welcome Remarks**	Regency Ballroom
8:15-9:00AM	**Day Three Keynote:** Innovative Pharmacovigilance When Resources are Scarce	Regency Ballroom
9:00-10:00AM	**Session 9:** Advanced Technologies	Regency Ballroom
10:00-10:45AM	Refreshment, Exhibits, and Networking Break	Ambassador Ballroom
10:45AM-12:15PM	**Session 10:** Regional Updates	Regency Ballroom
12:15-12:30PM	Q&A	Regency Ballroom
12:30-1:45PM	Luncheon, Exhibits, and Networking	Ambassador Ballroom
1:45-3:15PM	**Session 11:** Hot Topics	Regency Ballroom
3:15-3:30PM	**Closing Remarks**	Regency Ballroom
3:30PM	**Conference Adjourned**	

Learning objectives

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

- Apply the current regulatory framework for pharmacovigilance in key markets, including the US and the changing EU
- Examine the influence of recent regulatory developments and expectations in Japan, Canada, and Eurasia on safety and pharmacovigilance practice
- Discuss changes in pharmacovigilance and risk management resulting from the emergence of new and advanced technologies and therapies such as CAR-T cells, monoclonal antibodies, and gene therapy
- Describe pharmacovigilance and risk management considerations and approaches for combination products and rare disease therapies
- Apply frameworks and learnings from recent government and industry initiatives to improve safety monitoring and reporting in clinical trials
- Discuss challenges posed by the changing nature of safety data and the implications of new guidelines, such as the developing ICH E19 Guideline, and new approaches to pharmacovigilance and risk management, such as Artificial Intelligence/Machine Learning

Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 25.75 contact hours or 2.575 continuing education units (CEUs). Participants must attend the entire short course and/or all three days of the conference in order to be able to receive an ACPE statement of credit. No partial credit will be awarded.

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, MARCH 9, 2018.

Type of Activity: Knowledge

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 9, 2018**, 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. Obtain your NABP e-Profile at nabp.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 the up to 2.6 CEUs. Participants must attend the entire conference or short course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

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

This program is part of DIA's Certificate Program and is awarded the following:

- Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units

Credit Allocation

Short Courses

Short Course 1: *Periodic Benefit-Risk Evaluation Report (PBRER)*: Pharmacy 6.5 contact hours or .65 CEUs, UAN: 0286-0000-18-010-L04-P; IACET .65 CEUs

Short Course 2: *Pharmacovigilance and Risk Management Planning*: Pharmacy 6.5 contact hours or .65 CEUs, UAN: 0286-0000-18-011-L04-P; IACET .65 CEUs

Short Course 3: *Pharmacovigilance Inspections Part 1: Readiness, Conducting, Findings, and Report-Outs*: Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-18-012-L04-P; IACET .25 CEUs

Short Course 4: *Pharmacovigilance Inspections Part 2: Response, Measurement, Resolution, and Tracking:* Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-18-013-L04-P; IACET .25 CEUs

Conference

Pharmacy 19.25 contact hours or 1.925 CEUs, UAN: 0286-0000-18-014-L04-P; IACET 1.9 CEUs

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SHORT COURSES | SUNDAY, JANUARY 21

8:00AM-5:00PM — **Short Course Registration**

9:00AM-5:00PM — **Short Course 1:** PBRER

Instructors

Melissa Chan
Aggregate Report Analyst, Safety Evaluation and Reporting
Pfizer, Inc

Alison Turney, PharmD
Surveillance Business Process Advisor, Global Patient Safety
Eli Lilly and Company

Valerie E. Simmons, MD, FFPM
EU QPPV, Global Patient Safety
Eli Lilly and Company Ltd.,
United Kingdom

The instructors for this short course draw on experience from both direct involvement in the development of the ICH guideline itself, as well as from experts with extensive experience in actual implementation. This short course will cover the background and expectations behind key sections of the guideline and will provide an in-depth interpretation from the perspective of the expert working group that developed the concept. Based on this theoretic foundation, the course will then move to more practical aspects of implementation and lessons learned from experience since the PBRER format was first introduced. This will include the latest thinking and updates from the EU. The intent of this course is to be interactive and to tailor to your needs as much as possible. Questionnaires will therefore be sent to you to assess expectations based on level of experience as well as any key questions you wish the instructors to specifically address with the aim that answers are developed together in a coaching environment.

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

- Discuss the main principles defined in the ICH E2C(R2) guideline
- Describe the structure and content of the new PBRER
- Explain the regulatory authority expectations of the PBRER
- Recognize how to implement the PBRER to encompass multiple functions
- Discuss and evaluate the practical aspects in the preparation of the PBRER

9:00AM-5:00PM — **Short Course 2:** Pharmacovigilance and Risk Management Planning

Instructors

Stella C.F. Blackburn, MD, FRCP, FISPE, FFPM
Vice President, Global Head of Risk Management
IQVIA, United Kingdom

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc

This full-day short course 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 healthcare 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.

Learning Objectives
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

12:30-1:30PM — **Luncheon for Short Course Attendees**

9:00AM-12:30PM — **Short Course 3:** Pharmacovigilance Inspections Part 1: Readiness, Conducting, Findings, and Report-Outs

Instructors

Helen Powell
Principal Consultant
NDA Regulatory Science Ltd.,
United Kingdom

Shiferaw Kibriye, PharmD
Medical Quality Assurance, Head of Inspection Management
Pfizer Inc

Richard Abate, MS, RPh
Lead Consumer Safety Officer
FDA

Marcia Gelber, PharmD, RPh
Pharmacist, DHHS
FDA

Michael Richardson, MD, FFPM
International GPV&E and EU QPPV
Bristol-Myers Squibb,
United Kingdom

If a government investigator knocks on your door today, would your organization be ready for an inspection of your pharmacovigilance system? This short course will help familiarize you with the FDA inspection process so that an inspection can be effectively hosted and proactively managed. Hear two FDA experts and an EU expert explain how to be inspection ready, the Inspector's expectations, and common missteps that result in observations. In turn, learn perspectives from an industry veteran on what to do before and during an inspection. Course instructors will share practical and actionable commentary that you can use to improve and sustain your pharmacovigilance quality system.

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

- Explain the purpose behind pharmacovigilance inspections and their benefit(s)
- Describe the US and EU inspection processes and the differences/commonalities between the two
- Explain how to be inspection-ready
- Outline common inspection observations, including common EU findings
- Interpret messaging in FDA Untitled Letters and Warning Letters and EU inspection findings

SHORT COURSES | SUNDAY, JANUARY 21

1:30-5:00PM

Short Course 4: Pharmacovigilance Inspections Part 2: Response, Measurement, Resolution, and Tracking

**This short course follows on from the morning course, but can also be taken as a separate session.*

Instructors

Vicki Edwards, RPh
Vice President, Pharmacovigilance Excellence and QPPV
AbbVie, Inc., United Kingdom

Shiferaw Kibriye, PharmD
Medical Quality Assurance. Head of Inspection Management
Pfizer Inc

Helen Powell
Principal Consultant
NDA Regulatory Science Ltd., United Kingdom

The regulatory authority has just completed an inspection of your pharmacovigilance system and left you with a list of inspection observations. As you wait to receive the inspection report, when and how should you respond? Well-reasoned, complete, and timely responses are key to more positive outcomes of an inspection – in fact, they may make a difference in the final classification of an error or the type of regulatory correspondence issued. This short course will familiarize you with the principles and practical methods of planning and preparing an effective response to inspection observations, including: coordinated response preparation, assessment of underlying causes, development and implementation of corrective and preventive action plans (CAPAs), measurement, and tracking. Through hands-on case studies, you will have the opportunity to develop responses and action plans for the US and EU and to receive feedback on their work from regulators and qualified professionals.

Learning Objectives

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

- Describe common pharmacovigilance inspection observations
- Explain principles and guidelines for planning and preparing responses to inspection observations
- Plan and conduct a response to inspection observations, including development of a CAPA, measurement, and tracking

DAY ONE | MONDAY, JANUARY 22

7:15AM-5:30PM	**Registration**
7:15-8:15AM	**Continental Breakfast, and Networking**
8:15-8:30AM	**DIA Opening Remarks**
8:30-8:45AM	**Welcome Remarks** **Session Co-Chairs** **Stella C.F. Blackburn, MD, FRCP, FISPE, FFPM** Vice President, Global Head of Risk Management IQVIA, United Kingdom **William W. Gregory, PhD** Senior Director, Worldwide Safety and Regulatory Pfizer Inc
8:45-9:30AM	**Opening Keynote:** Patient Advocacy in Rare Disease: Duchenne Muscular Dystrophy **Session Chair** **William W. Gregory, PhD** Senior Director, Worldwide Safety and Regulatory Pfizer Inc Rare diseases present special challenges for patients, caregivers, and those who seek to develop and provide safe and effective treatments. One disease that presents such challenges is Duchenne Muscular Dystrophy (DMD), a genetic disorder that is characterized by progressive muscle degeneration and weakness caused by an abnormality in the dystrophin complex in muscle fiber. Development of safe and effective biopharmaceutical interventions has been enigmatic. This session will provide an overview of this devastating disease, patient advocacy efforts, and the partnership network that has emerged to facilitate development of evidence-based interventions. **Christine McSherry, RN** Executive Director The Jett Foundation

DAY ONE | MONDAY, JANUARY 22

9:30-11:00AM

Session 1: FDA Updates

Session Chair

Gerald J. Dal Pan
Director, Office of Surveillance and Epidemiology
CDER, FDA

FDA representatives will provide updates from the Office of Surveillance and Epidemiology (OSE) within CDER and the Office of Biostatistics and Epidemiology in CBER. Topics will include post-marketing safety monitoring, an overview of pharmacoepidemiology, pharmaceutical risk management, medication error prevention, and updates on safety surveillance from the Office of Generic Drugs.

New Developments in Pharmacovigilance
Gerald J. Dal Pan
Director, Office of Surveillance and Epidemiology
CDER, FDA

An FDA Update on Pharmacovigilance and Risk Management Approaches for CBER-Regulated Biologic Products
Steven Anderson PhD, M.P.P.
Director, Office of Biostatistics and Epidemiology
CBER, FDA

Experiences in Safety and Surveillance of Generic Drugs
John Peters, MD
Deputy Director, Office of Generic Drugs
CDER, FDA

Howard D. Chazin, MD, MBA
Medical Officer, Clinical Safety and Surveillance
Office of Generic Drugs
CDER, FDA

11:00-11:30AM

Refreshments, Exhibits, and Networking Break

11:30AM-12:30PM

Session 2: The New ICH

Session Chair

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc

Since 1990, the International Conference on Harmonisation (ICH) has provided a consensus forum for drug regulators and the pharmaceutical industry to develop harmonized of scientific and technical requirements for registration of innovative pharmaceutical products. In October 2015, ICH announced organizational and process changes to expand formal participation of organizations beyond the EU, Japan, and the US. Further changes to the face of global biopharmaceutical product development were made in June 2017. This session will provide an overview of the current ICH. In addition, regulator and industry perspectives will be presented on global harmonization of a new topic, E-19 (optimization of safety data collection).

Overview of the Current ICH
Amanda Marie Roache, MS
Operations Research Analyst, OSP
CDER, FDA

The New ICH E19 Guideline on Optimization of Safety Data Collection (in Development): Regulatory Perspective
Ellis Unger, MD
Director, Office of Drug Evaluation I, OND
CDER, FDA

12:30-2:00PM

Luncheon and Round Table Discussions

2:00-3:30PM

Session 3: Operational Hot Topic: Machine Learning/Artificial Intelligence in Pharmacovigilance

Session Co-Chairs

Mariette Boerstoel-Streefland, MD
Senior Vice President, Head Global Drug Safety
Shire

Bruce Donzanti, PhD
Senior Group Director
Global Pharmacovigilance Innovation Policy
Genentech Inc., A Member of the Roche Group

This session will provide a brief introduction on the need for new technologies to address the growing concerns around the ability to assess the ever-increasing volumes of data for valuable safety information, the applicability of ML/AI to address this concern, and will bring in perspectives from regulatory authorities, pharma industry, and a technology innovator, to conclude with a panel discussion on where we are going with the application of ML/AI in pharmacovigilance.

Bruce Donzanti, PhD
Senior Group Director
Global Pharmacovigilance Innovation Policy
Genentech Inc., A Member of the Roche Group

New Kid on the Block: Machine Learning and Why it's Important for Pharmacovigilance
Shaun Comfort, MD, MBA
Associate Director and Senior Safety Science Leader IIDO
Genentech, A Member of the Roche Group

Machine Learning Use Cases
Elenee Argentinis, JD
Offering Leader, IBM Watson for Patient Safety
Watson Health Life Sciences Solutions

Shaun Comfort, MD, MBA
Associate Director and Senior Safety Science Leader IIDO
Genentech, A Member of the Roche Group

Regulatory Perspective on Machine Learning in Pharmacovigilance
Robert Ball, MD, MPH
Deputy Director, Office of Surveillance and Epidemiology
CDER, FDA

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
Medicines and Healthcare products Regulatory Agency (MHRA), EU

Panel Q&A

DAY ONE | MONDAY, JANUARY 22

3:30-4:00PM — **Refreshments, Exhibits, and Networking Break**

4:00-5:30PM — **Session 4:** Combination Products

Session Chair

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

Combination products are therapeutic and diagnostic products that combine drugs, devices, and or biological products. Because combination products involve multiple components, they are associated with new regulatory, policy, development, and review challenges. In this session, we explore some of these emerging challenges with combination products, such as adverse event reporting and principles of human factor studies during the development of combination products.

Safety Reporting Rule for Combination Products

Representative Invited
FDA

Technical Specifications for Safety Reporting of Combination Products

Suranjan De, MBA, MS
Deputy Director, Regulatory Science, OSE
CDER, FDA

Khaudeja Bano, MD, MS
Senior Medical Director, Medical Affairs, Diagnostics
Abbott Laboratories

5:30-6:30PM — **Networking and Exhibits Reception**

6:30-9:00PM — **Dine Arounds**

DAY TWO | TUESDAY, JANUARY 23

7:30AM-6:00PM — **Registration**

7:30-8:30AM — **Continental Breakfast, Exhibits, and Networking**

8:30-8:45AM — **Welcome Remarks**

8:45-9:30AM — **Day Two Keynote:** Data Rich, Information Poor – Can We Turn Health Records into a Truly Learning Healthcare System?

Session Chair

Stella C.F. Blackburn, MD, FRCP, FISPE, FFPM
Vice President, Global Head of Risk Management
IQVIA, United Kingdom

We are being deluged by data from many different sources, but are we using it to improve outcomes for patients? This session will cover what a learning healthcare system is and where we are in implementation. It will also explore personalized medicine and whether regulators, payers, and healthcare systems can keep up with the challenges of rapid progress in medicine.

Hans-Georg Eichler, MD, MSc
Senior Medical Officer
European Medicines Agency, European Union

9:30-11:00AM — **Session 5:** EU Updates

Session Co-Chairs

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
Medicines and Healthcare products Regulatory Agency (MHRA), European Union

Hans-Georg Eichler, MD, MSc
Senior Medical Officer
European Medicines Agency, European Union

Regulations and expectations for pharmacovigilance in the EEA continue to evolve. This session will explore recent developments related to post-marketing pharmacovigilance as well as the practice of drug safety during clinical trials. The focus will be on the evolving situation in the EEA, set in a global context.

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
Medicines and Healthcare products Regulatory Agency (MHRA), European Union

Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence
AbbVie, Inc., United Kingdom

Valerie E. Simmons, MD, FFPM
MD, FFPM EU QPPV, Global Patient Safety
Eli Lilly and Company Ltd., United Kingdom

11:00-11:30AM — **Refreshments, Exhibits, and Networking Break**

DAY TWO | TUESDAY, JANUARY 23

11:30AM-12:45PM

Session 6: Clinical Trial Issues

Session Chair

Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management
United BioSource Corporation

The current regulatory framework and expectations for good pharmacovigilance practices are changing in key markets, which create new challenges for all stakeholders. This session will examine the expanding importance of patient perspectives on tolerability as the safety profile of an investigational product is developed. In addition, progress on global harmonization of pragmatic safety requirements will be addressed.

Use of Common Toxicity AE Terminology and Patient-Reported Outcomes in Clinical Trials
Sandra Mitchell, PhD, CRNP
Research Scientist and Program Director, Outcomes Research Branch, Division of Cancer Control and Population Sciences
National Cancer Institute

Global Harmonization of Pragmatic Safety Requirements, with Information from the Transcelerate Project
Robert M. Baker
Vice President, Global Patient Safety
Eli Lilly & Company

Sadiqa Hafeez Mian, MD, MPH
Head Safety Management
Amgen Inc.

Effect on the Clinical Trial Regulations on Post-Authorization Safety Studies (PASS)
Michelle Bulliard, BSN
Vice President, Global Head Real-World Evidence Strategy Unit
IQVIA, Switzerland

12:45-2:00PM

Luncheon, Exhibits, and Round Table Discussions

2:00-2:45PM

Mid-Day Keynote

Session Chair

Simone P. Pinheiro, PhD
Lead Epidemiologist
FDA

The FDA is committed to facilitating rapid development, review and action on promising cancer treatments. This exciting DIAmond session will discuss recent progresses and novel approval pathways for oncology therapeutic products, including real world evidence. This session will also discuss the Oncology Center of Excellence, developed as part of the 21st Century CURES Act, and its role in the development of regulatory approaches to expedite drug development. This 45-minute session will be composed of two presentations followed by Q&A.

Novel Approaches in Oncology Products
Sean Khozin, MD, MPH
Associate Director (Acting), Oncology Center of Excellence
CDER, FDA

Oncology Center of Excellence
Tamy Kim, PharmD
Associate Director, Regulatory Affairs, Office of Hematology and Oncology Products, OCE (Acting)
CDER, FDA

2:45-4:15PM

Session 7: Update on New Treatments

Session Chair

Stella C.F. Blackburn, MD, FRCP, FISPE, FFPM
Vice President, Global Head of Risk Management
IQVIA, United Kingdom

Pharmacovigilance is similar to a detective story. We are trying to determine whether the adverse event is due to a drug, the diseases the patient is being treated for or something intrinsic to the patient. To do this we need an understanding of both the drug mechanisms of action and the context in which drug is used. New classes of treatments are being developed all the time with increasingly complex and specific mechanisms. This session will provide an overview of three emerging therapies from a clinical point of view: CAR-T cells, monoclonal antibodies – targeted therapies and checkpoint inhibitors – and gene therapy.

David Chonzi
Vice President, Patient Safety and Risk Management
Kite, A Gilead Company

Jacques P. Tremblay, PhD
Deputy Editor, Molecular Therapy and Cell Transplantation; Professor, Department of Molecular Medicine
Laval University, Canada

Jeff Anderson, MD, PhD
HCC Program Lead, Oncology Clinical Development
Bristol-Myers Squibb

4:15-4:45PM

Refreshments, Exhibits, and Networking Break

4:45-6:00PM

Session 8: Advanced Therapeutics Pharmacovigilance and Risk Management

Session Chair

Barbara Morollo
Head, Pharmacovigilance Operations
Moderna Therapeutics

The development of ATMPs has sparked considerable interest and debate as there are many unknowns and uncertainties concerning the effects or responses these therapies may evoke, especially in the case of genetic manipulation.

This session will examine the challenges associated with monitoring safety and the benefit-risk of these therapies, both short-term and long-term, and explore the complexities associated with determining the safety profile and benefit-risk across common delivery platforms such as gene therapy vectors and lipid nanoparticle delivery systems.

Common Technical Platforms: Benefit-Risk Determination and Risk Management
Barbara Morollo
Head, Pharmacovigilance Operations
Moderna Therapeutics

Jaspal Ahluwalia, MD
Medical Officer
FDA

Adrian Dana, MD
Vice President, Global Patient Safety and Risk Management at Alnylam
Alnylam Pharmaceuticals Cambridge

Michael Richardson, MD, FFPM
International GPV&E and EU QPPV
Bristol-Myers Squibb, United Kingdom

DAY THREE | WEDNESDAY, JANUARY 24

7:00AM-3:30PM — **Registration**

7:00-8:00AM — **Continental Breakfast, Exhibits, and Networking**

8:00-8:15AM — **Welcome Remarks**

8:15-9:00AM

Day Three Keynote: Innovative Pharmacovigilance when Resources are Scarce

Session Chair

Lesley Wise, PhD, MSc
Managing Director
Wise Pharmacovigilance and Risk Management Ltd., United Kingdom

Pharmacovigilance capacity building in low- to middle-income countries requires innovative methods and a willingness to prioritize in a different way to the countries where PV guidances are often first issued. The health considerations are different, the communication technologies are different, and public health emergencies often stretch the scarce resources. Eric Perakslis, PhD, will share his perspectives and experience from working with a range of NGOs including MSF and developing data collection systems during the Ebola crisis.

Keynote Speaker

Eric D. Perakslis, PhD
Senior Vice President, Informatics
Takeda Pharmaceuticals

9:00-10:00AM

Session 9: Advanced Technologies

Session Chair

Stephen Knowles, MD, MRCP
Vice President, Drug Safety and Pharmacovigilance
Halozyme

The use of advanced technologies in the management of chronic diseases and monitoring patients in clinical trials is increasing. For example, the use of mobile apps to aid the control of diabetes, the use of wearable technologies to monitor patient sleep and activity during clinical trials, and implantable biosensors which allow continuous monitoring of body chemicals. This session will bring scientific expert and patient perspectives together in a discussion of these new technologies and the impact they are having, and will have, on patient monitoring and patient experience.

The Use of Wearable Technologies in Clinical Trials to Monitor Movement and Sleep/ Wake Patterns

Gary Zammit, PhD, MS
President and CEO
Clinilabs Inc.

Sara Loud, MBA, MS
Chief Operating Officer
Accelerated Cure Project

10:00-10:45AM — **Refreshments, Exhibits, and Networking Break**

10:45AM-12:15PM

Session 10: Regional Updates

Session Chair

E. Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Director, Corporate Medical Affairs HQ
Eisai Co., Ltd.

This session focuses on countries or regions where pharmacovigilance regulations are in transition or where recent updates can present compliance issues for clinical trial Sponsors or Marketing Authorization Holders. The Eurasian Economic Union (EAEU), which includes Russia and a number of states in northern Eurasia, now has a Good Pharmacovigilance Practice (GVP) guideline and requirement for a QPPV, which will be described and explained. In Japan the "Three Officer System" is undergoing revisions in the face of a number of compliance issues that have surfaced in that country and the countries Good Postmarketing Survey Practice (GPSP) is also being modified. An update on the implementation of Vanessa's Law (the Protecting Canadians from Unsafe Drugs Act), one of the most significant changes to the Canadian Food and Drug Act in 50 years, and its implications for pharmacovigilance in that country will also be presented.

The Evolving Situation in Japan: The "Three Officer System" and GPSP

Shinobu Uzu, MSc
Chief Safety Officer
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Modernization Efforts in Canada: The Regulatory Review of Drugs and Devices and Vanessa's Law

Melissa Hunt, MSc
Scientific Manager
Health Canada

CRO Perspectives on New PV Requirements in the EAEU

Simon Johns
Product Specialist, Director, Lifecycle Safety and Marketed Products Maintenance
IQVIA, United Kingdom

What New EAEU PV Obligations Mean for a Global Company with a Focus on Russia

Tatyana Prokhorova, MD, PhD
EAEU/Ukraine QPPV, Cluster Safety Lead
Pfizer LLC, Russia

12:15-12:30PM — **Q&A**

DAY THREE | WEDNESDAY, JANUARY 24

12:30-1:45PM	**Luncheon, Exhibits, and Networking**
1:45-3:15PM	**Session 11:** Hot Topics **Session Chair** **Michael Richardson** International GPV&E and EU QPPV Bristol-Myers Squibb, United Kingdom This session will cover areas of drug safety which are problematic and require industry and regulators to work together in managing data in the post-approval space, in particular from multiple sources, both structured and unstructured data collection activities. Speakers will present on projects looking at what data can be of value to identifying signals and safety evaluation, how to manage real-world data such as the sentinel programs, and how best to utilize the specific risk management effectiveness evaluations through moving to a digital platform. Speakers will present on their topics then a joint panel for a Q&A will take place. **Vicki Edwards** QPPV and Head of Affiliate Vigilance Excellence AbbVie, Inc. **Sentinel ARIA Process** **Tyler Coyle, MD, MS** FDA Sentinel Core Team, OSP CDER, FDA **Digital Approach to Risk Minimization** **Mark Perrott, PhD** Head of Development Consulting Pope Woodhead & Associates Ltd, United Kingdom **Value of Safety Information Data Sources** **Jeremy Jokinen, PhD, MS** Senior Director, Safety Decision Analytics AbbVie, Inc. **Peter Verdru, MD** Vice President, Head of Patient Safety UCB Biopharma S.P.R.L., Belgium
3:15-3:30PM	**Closing Remarks**
3:30PM	**Conference Adjourned**


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