Pharmacovigilance and Risk Management Strategies 2016

Tutorials: January 24 | Conference: January 25-27 | Mandarin Oriental Washington D.C. | Washington, DC

PROGRAM CO-CHAIRS:

William W. Gregory, PhD
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Pfizer Inc.

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

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Overview

The health care delivery system continues to evolve to provide ever-enhanced value to patients. This requires a shift in regulatory science, tools, realities, and perceptions of biopharmaceutical product benefit-risk across the global pharmacovigilance landscape. It is more important than ever to find ways to fully harness innovation and adopt new technologies to advance pharmacovigilance practices.

Top pharmaceutical, biotechnology, and regulatory thought leaders from around the globe convene each January to provide their insights and engage in dialogue on current and potential new opportunities, operational challenges, and practical aspects, as well as demands in managing product risk in the context of benefits, in the ever-changing world of medical product safety, pharmacovigilance, and global regulations.

Highlights

KEYNOTE SPEAKER:

Mark McClellan, MD, PhD
Director of the Duke-Robert J. Margolis, MD, Center for Health Policy;
Robert J. Margolis Professor of Business, Medicine and Health Policy

- Global Regulatory Safety Updates
- New Data Sources for Safety Assessment
- Current Approaches to Benefit-Risk Assessment
- Luncheon Round Table Discussions with Key Thought Leaders
- Tabletop Exhibits
- Four Tutorial Offerings on Sunday, January 24
- Unique Opportunity to Interact with Representatives from FDA and other Key Regulatory Agencies, Industry, and Academia
- Numerous Networking Opportunities

Message from Program Co-Chairs

On behalf of the Program Committee and DIA Board of Directors, we are both delighted and honored to invite you to DIA's annual conference on drug safety, Pharmacovigilance and Risk Management Strategies 2016. In creating this program, our aim has been to develop a visionary keynote, eleven wickedly good scientific sessions, and four in-depth tutorials, all presented by authoritative, world-class experts. Our keynote address will be delivered by Dr. Mark McClellan, who, amongst other positions, has served as FDA Commissioner and Director of Health Care Innovation and Value Initiatives at the Brookings Institution. He is currently Director of the Duke-Robert J. Margolis, MD, Center for Health Policy. As in years past, this year's program will incorporate emerging topics in biopharmaceutical safety and advances in regulatory science; the program offers an unmatched opportunity for discussion, cross-collaboration, networking, and professional advancement. The primary purpose of all of these sessions is educational and sessions are intended to inform by professionals who are willing to share their experiences with colleagues. We are also excited to announce that the popular Round Table Lunch Discussions have been expanded to accommodate more participants. In addition, exhibitors will showcase their latest products and services in drug safety and are a can't-miss destination when the plenary is not in session.

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

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

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Schedule At-A-Glance

TUTORIALS | SUNDAY, JANUARY 24, 2016

8:30 AM–12:00 PM	Tutorial #2 – FDA Adverse Event Reporting System (FAERS): Individual Case Safety Reports (ICSR) and Data Quality
10:00 AM–5:00 PM	Tutorial #1 – Pharmacovigilance and Risk Management Planning
1:30–5:00 PM	Tutorial #3 – Periodic Benefit-Risk Evaluation Report (PBRER)
1:30–5:00 PM	Tutorial #4 – Principles and Practice of Pharmacovigilance Governance

DAY ONE | MONDAY, JANUARY 25, 2016

7:30 AM–6:00 PM	Attendee Registration
7:30–8:30 AM	Continental Breakfast in Exhibit Hall
8:30–8:45 AM	Welcome and Opening Remarks
8:45–10:00 AM	Session 1 – Keynote Address
10:00–10:30 AM	Refreshment Break and Networking in Exhibit Hall
10:30 AM–12:00 PM	Session 2 – FDA Updates
12:00–1:30 PM	Luncheon in Exhibit Hall and Round Table Discussions
1:30–3:00 PM	Session 3 – Maturing Markets Regulatory Updates
3:00–3:30 PM	Refreshment Break and Networking in Exhibit Hall
3:30–5:00 PM	Session 4 – New Data Sources
5:00–6:00 PM	Networking Reception in Exhibit Hall

DAY TWO | TUESDAY, JANUARY 26, 2016

7:30 AM–5:00 PM	Attendee Registration
7:30–8:30 AM	Continental Breakfast in Exhibit Hall
8:30–10:00 AM	Session 5 – EU Regulatory Updates
10:00–10:30 AM	Refreshment Break and Networking in Exhibit Hall
10:30 AM–12:00 PM	Session 6 – Blinding/Unblinding
12:00–1:30 PM	Luncheon in Exhibit Hall and Round Table Discussions
1:30–3:00 PM	Session 7 – Benefit-Risk
3:00–3:30 PM	Refreshment Break and Networking in Exhibit Hall
3:30–5:00 PM	Session 8 – Customer Engagement Programs

DAY THREE | WEDNESDAY, JANUARY 27, 2016

7:30 AM–3:00 PM	Attendee Registration
7:30–8:30 AM	Continental Breakfast in Exhibit Hall
8:30–10:00 AM	Session 9 – Biosimilars
10:00–10:30 AM	Refreshment Break and Networking in Exhibit Hall
10:30 AM–12:00 PM	Session 10 – Advanced Therapies
12:00–1:30 PM	Luncheon in Exhibit Hall
1:30–3:00 PM	Session 11 – HOT TOPIC PANEL: Earlier Access vs. Additional Safety?
3:00 PM	Conference Adjourns

Learning Objectives

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

- Employ the current regulatory framework for pharmacovigilance in key markets
- Utilize various aspects of Customer Engagement Programs, such as patient support programs (PSPs) for collection and management of safety data
- Discuss how advanced therapies and new approaches may impact pharmacovigilance and risk management
- Describe how new data sources and new technologies effect safety data management
- Examine new trends and approaches for the safety assessment of biosimilars

Continuing Education Credits

Corexcel is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Corexcel designates this activity for a maximum of 23 contact hours.

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

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Postgraduate Institute for Medicine (PIM) and DIA. PIM is accredited by the ACCME to provide continuing medical education for physicians.

PIM designates this live activity for a maximum of 16.5 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for 20 contact hours or 2.0 continuing education units (CEU's).

ALL ACPE CREDIT REQUESTS MUST BE SUBMITTED THROUGH DIA'S MY TRANSCRIPT BY FRIDAY, MARCH 11, 2016. 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**. 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.

If you would like to receive a statement of credit, you must sign in at the registration desk each morning, and complete the online credit request process through My Transcript. My Transcript will be available for credit requests beginning **Wednesday, February 10, 2016**. To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
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The evaluation closes on **Wednesday, February 17, 2016.**

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Continuing Education Credit Allocation

Tutorials:
Tutorial #1 – Pharmacovigilance and Risk Management Planning: IACET: .6 CEUs; Nursing: 5.75 contact hours; Pharmacy: 5.75 contact hours or .575 CEUs, 0286-0000-16-004-L04-P; Type of activity: Knowledge
Tutorial #2 – FDA Adverse Event Reporting System: Individual Case Safety Reports and Data Quality: IACET: .3 CEUs; Nursing: 3.25 contact hours; Pharmacy: 3.25 contact hours or .325 CEUs, 0286-0000-16-005-L04-P; Type of activity: Knowledge
Tutorial #3 – Periodic Benefit-Risk Evaluation Report: IACET: .3 CEUs; Nursing: 3.25 contact hours
Tutorial #4 – Principles and Practice of Pharmacovigilance Governance: IACET: .3 CEUs; Nursing: 3.25 contact hours; Pharmacy: 3.25 contact hours or .325 CEUs, 0286-0000-16-006-L04-P; Type of activity: Application

Conference:
CME: 16.5 *AMA PRA Category 1 Credits™*
Nursing: 16.5 contact hours
IACET: 1.7 CEUs
Pharmacy Credit Allocation:

- Welcome, Sessions 1, 2, and 4: 4.5 contact hours or .45 CEUs, 0286-0000-16-007-L05-P; Type of activity: Knowledge
- Sessions 6, 7, and 8: 4.5 contact hours or .45 CEUs, 0286-0000-16-008-L05-P; Type of activity: Knowledge
- Sessions 9, 10, and 11: 4.5 contact hours or .45 CEUs, 0286-0000-16-009-L05-P; Type of activity: Knowledge

SUNDAY, JANUARY 24, 2016

FULL DAY TUTORIAL

10:00 AM–5:00 PM
(Box lunch will be served)

Tutorial #1 – Pharmacovigilance and Risk Management Planning

Instructors

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

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

POLLING: Use the DIA App

This full day tutorial 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.

Learning Objectives

At the conclusion of this tutorial, 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

HALF DAY TUTORIALS

8:30 AM–12:00 PM
(Lunch is not provided for half day tutorial attendees)

Tutorial #2 – FDA Adverse Event Reporting System (FAERS): Individual Case Safety Reports (ICSR) and Data Quality

Instructors

Roger A. Goetsch, PharmD
Pharmacist, Office of Surveillance & Epidemiology
CDER, FDA

Suranjan De, MS, MBA
Deputy Director, Regulatory Science, Office of Surveillance & Epidemiology, CDER, FDA

Sonja Brajovic, MD
Medical Officer, Office of Surveillance & Epidemiology
CDER, FDA

Jo Wyeth, PharmD
Pharmacist , Office of Surveillance and Epidemiology

This half day tutorial will provide an overview and lessons learned regarding the submission and evaluation of postmarketing case safety reports in electronic format to the FAERS database, both through the "database-to-database" E2B process, and through the Safety Reporting Portal. The tutorial will then discuss specific data quality issues with an in-depth focus on suspect product identification and on submitted MedDRA coding for adverse events and medication errors. Additionally, an update on the status of the E2B(R3) Technical Specifications Document and electronic vaccine case reporting shall be presented.

Learning Objectives

At the conclusion of this tutorial, participants will be able to:

- Describe electronic case reporting to FAERS
- Explain data quality issues encountered with electronic ICSR submissions
- Discuss data quality issues related to suspect product identification, using examples
- Discuss data quality issues related to MedDRA coding for adverse events and medication errors, using examples

1:30–5:00 PM

Tutorial #3 – Periodic Benefit-Risk Evaluation Report (PBRER)

Instructors

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

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

Stephen Knowles, MD, MRCP
Senior Director
Global Patient Safety
Eli Lilly and Company

This half day tutorial will cover experience in operationalizing the ICH E2C(R2) PBRER guideline since November 2012, when the guideline reached ICH Step 4. The guideline is now at ICH Step 5, having been implemented in the EU. Indeed, the PBRER format, content, and analytical focus are accepted in many countries, including the US and Japan. Further, the PBRER may eventually replace certain other requirements for postmarketing safety data and analysis, which could make the pharmacovigilance enterprise more efficient in transferring value to patients. While this presents an opportunity to advance patient safety, practical challenges must be overcome by regulators, MAHs, and service providers. In addition, assessment reports are now becoming available for use in a continuous improvement mode. This new report represents a significant change from the previous PSUR format and a quantum leap forward to a document that incorporates many new concepts including an integrated evaluation of both benefits and risks of a medicinal product.

Learning Objectives

At the conclusion of this tutorial, 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 some of the key implementation challenges and how they may be addressed
- Discuss practical aspects in the preparation of the PBRER

1:30-5:00 PM

Tutorial #4 – Principles and Practice of Pharmacovigilance Governance

Instructors

Kelly Traverso
Specialist Leader
Deloitte

Deirdre McCarthy
Senior Benefit Risk Management Director
Quintiles Inc.

JP Clement, MD
Principal
J.P. CLEMENT CONSULTING LLC

Even if safety is everyone's responsibility, this message is sometimes lost in the complexity of day-to-day business activities of a pharmaceutical organization. Health Authorities have issued 483s and warning letters directing companies to establish safety governance models to assure that patient safety is always front and center regardless other strategic and operational priorities. A company Safety Governance Model should be:

- Cross-functional – Safety is every employee's and function's responsibility
- Across the extended enterprise – Responsibility extends to partners, suppliers, affiliates, and distributors
- Leadership-driven – The governance model is led by senior leadership, and includes clinical, medical, quality, and safety officers
- Periodic and predictable – The committees and processes are executed on a periodic basis as defined in the charters and SOPs
- Inclusive of people, process, and technology – The model embodies organizational structure, safety-related processes and tools, and technology to support patient safety

During the tutorial, instructors will present a case study on implementing a safety governance model.

Learning Objectives

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

- Define the basic principles of a safety governance model
- Discuss the broad scope of pharmacovigilance responsibilities across the enterprise
- Explain how all of the areas across the extended enterprise are impacted by a safety governance model

MONDAY, JANUARY 25, 2016

7:30 AM-6:00 PM Attendee Registration

7:30-8:30 AM Continental Breakfast in Exhibit Hall

8:30-8:45 AM

Welcome and Opening Remarks

Barbara Lopez Kunz
Global Chief Executive
DIA

Program Co-Chairs

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

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

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8:45-10:00 AM

Session 1 – Keynote Address

Session Co-Chairs

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

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

Keynote Speaker

How Can Drug Safety Promote Innovation in Health Care?

Mark McClellan, MD, PhD
Director of the Duke-Robert J. Margolis, MD, Center for Health Policy;
Robert J. Margolis Professor of Business, Medicine and Health Policy

10:00-10:30 AM Refreshment Break and Networking in Exhibit Hall

10:30 AM-12:00 PM

Session 2 – FDA Updates

Session Chair

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

In this session, FDA representatives will provide updates from the Office of Surveillance and Epidemiology (OSE) within CDER. Topics will include postmarketing safety monitoring within OSE, an overview of pharmacovigilance, pharmacoepidemiology, pharmaceutical risk management, and medication error prevention.

Postmarketing Drug Safety at FDA

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

REMS Update

Claudia Manzo, PharmD
Director, Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
CDER, FDA

REMS Compliance

Chrissy J. Cochran, PhD
Director (Acting), Division of Enforcement and Postmarketing Safety,
Office of Compliance, Office of Scientific Investigations
CDER, FDA

12:00-1:30 PM Luncheon in Exhibit Hall

Round Table Lunch Discussions

There will be a 30 minute session for a limited number of participants to join Round Table discussions during the lunch break. Key thought leaders will help facilitate the discussion.

Topic #1 – Transition to the Evolving EU PV Legislation

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

Topic #2 – Tell it to the Regulator: Share Your Challenges and Successes on Implementation of the EU PV Legislation

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

Topic #3 – FDA Project JumpStart

John A. Saunders
Sr. Business Systems Consultant
Abbvie, Inc.

Topic #4 – eReporting

Roger A. Goetsch, PharmD
Pharmacist, Office of Surveillance & Epidemiology
CDER, FDA

Suranjan De, MS, MBA
Deputy Director, Regulatory Science, Office of Surveillance & Epidemiology, CDER, FDA

Topic #5 – VigiAccess – The Public Access to the WHO ICSR Database

Marie Lindquist, MD
Director
Uppsala Monitoring Centre

Topic #6 - Triggers for Modifying REMS

Jamie Wilkins Parker, PharmD
Team Leader, Office of Surveillance and Epidemiology
CDER, FDA

Topic #7 - MedDRA Coding and Suspect Product Reporting

Sonja Brajovic, MD
Medical Officer, Office of Surveillance & Epidemiology,
CDER, FDA

1:30-3:00 PM

Session 3 – Maturing Markets Regulatory Updates

Session Chair

Stewart Geary, MD
Chief Medical Officer, Senior Vice President
Eisai Co., Ltd., Tokyo, Japan

This session will provide an introduction to regulations and practices for pharmacovigilance and risk management in the Middle East, Latin America, and Russia, including requirements for expedited and periodic reporting during clinical development and post-marketing and any requirements for Risk Management Plans. It will also give a focused description of current challenges for pharmacovigilance and risk management in Northeast Asia (China, Japan, Korea) and what companies need to do to assure regulatory compliance.

New PV Regulations: Eurasian Economic Union & Arab Countries

Isobel Reid
Regional Director Pharmacovigilance, Intercon, Australia and Canada
Bristol-Myers Squibb

Pharmacovigilance in Brazil

Cristiane Pasin, Pharm D
Country Safety Lead
Pfizer

Pharmacovigilance Compliance Challenges in China, Korea, and Japan

Stewart Geary, MD
Chief Medical Officer, Senior Vice President
Eisai Co., Ltd., Tokyo, Japan

3:00-3:30 PM Refreshment Break and Networking in Exhibit Hall

3:30-5:00 PM

Session 4 – New Data Sources

Session Chair

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

POLLING: Use the DIA App

Despite limitations, the Spontaneous Reporting System has been a valuable tool in the discovery of important safety signals since the 1960s. In recent years, however, rapidly evolving digital technology has spawned extensive exploratory work with the goal of uncovering new and potentially impactful patterns of harms. This session will explore three emerging tools: The voice of the patient from the perspectives of patient advocacy and FDA; a new surveillance system that allows FDA to collect AEs in real time during emergencies; and vision for an MHRA-led, public-private partnership that would harness mobile technologies and the Internet for pharmacovigilance.

Perspectives on the Voice of the Patient: PatientsLikeMe

Sally Okun
Vice President, Advocacy, Policy and Patient Safety
PatientsLikeMe

PatientsLikeMe and FDA Research Collaboration – Regulatory Perspective

Marni Hall, PhD, MPD
Director, Regulatory Science Staff
Office of Safety and Epidemiology
CDER, FDA

Real-time Applications for Programmable Interactive Devices (RAPID) System at FDA

Henry "Skip" Francis, MD
Director for Data Mining and Informatics Evaluation and Research, Office of Translational Sciences
CDER, FDA

The Promise of Social Media for Pharmacovigilance as Envisioned by WEB-ADR

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

5:00-6:00 PM Networking Reception in Exhibit Hall

Join DIA social media expert Rebecca Pollard for our #PVRMS16 Tweetup in the Hillwood Room. Learn how to maximize your social media presence for networking and connecting with new colleagues at the conference through your social media channels.

TUESDAY, JANUARY 26, 2016

7:30 AM-5:00 PM Attendee Registration

7:30-8:30 AM Continental Breakfast in Exhibit Hall

8:30-10:00 AM **Session 5 – EU Regulatory Updates**

Session Co-Chairs

Stephen Knowles, MD, MRCP
Senior Director
Global Patient Safety
Eli Lilly and Company

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

This session will provide up to date reviews of aspects of EU legislation from the perspective of the EMA and Industry.

You will hear from a member of the MHRA on initiatives to move beyond the implementation of the new pharmacovigilance legislation to enable the operation of the requirements to the highest possible standards against agreed standards and best practice - The SCOPE project, a three year EU-wide pharmacovigilance project, is being coordinated by the MHRA to help member states meet the requirements of the new pharmacovigilance legislation. The second presentation, given by an industry representative, will look at the implications of the new CT regulations for PASS studies, both interventional and non-interventional. The final presentation will be a view from the EMA on regulatory pathways for adaptive licensing, an increasingly important way to make medicines available quickly for life-threatening diseases where there is no currently available effective treatment.

SCOPE Project

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

The New EU CT Regulations: Implications for Interventional and Non-Interventional PASS

Michelle Bulliard
Vice President, Global Head Real-World Evidence Strategy Unit
Quintiles Inc.

Adaptive Pathways

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

10:00-10:30 AM Refreshment Break and Networking in Exhibit Hall

10:30 AM-12:00 PM **Session 6 – Blinding/Unblinding**

Session Chairs

JP Clement, MD
Principal
J.P. CLEMENT CONSULTING LLC

Mat Soukup, PhD
Statistics Team Lead, Division of Biometrics VII, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Regulatory Authorities such as FDA and EMA provide directions or recommendations on reporting and unblinding clinical trial safety reports to authorities, investigators, and IRBs. While unblinding reports is key for identifying any change in the safety profile of an investigational drug, it is important to balance between the need for maintaining trial integrity and identifying and alerting on any potential safety issue. The session will provide practical aspects and perspectives from industry leaders and data monitoring committees on the applied implementation of the different guidances and recommendations.

How to Monitor Safety in Blinded Clinical Trials

Brenda Crowe, PhD
Senior Research Advisor, Global Statistical Sciences
Eli Lilly and Company

Statistical Approaches to Looking at Blinded Data and Detecting Signals

Greg Ball, PhD
Principal Biostatistician
Merck & Co., Inc.

Perspective From a DMC

Janet Turk Wittes, PhD
President
Statistics Collaborative Inc.

12:00-1:30 PM Luncheon in Exhibit Hall

Round Table Lunch Discussions

There will be a 30 minute session for a limited number of participants to join Round Table discussions during the lunch break. Key thought leaders will help facilitate the discussion.

Topic #1 – Transition to the Evolving EU PV Legislation

Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence
AbbVie Ltd

Topic #2 – Tell it to the Regulator: Share Your Challenges and Successes on Implementation of the EU PV Legislation

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

Topic #3 – FDA Project JumpStart

Crystal Allard
Consumer Safety Officer, OCS, OC
FDA

John A. Saunders
Sr. Business Systems Consultant
Abbvie, Inc.

Topic #4 – Meta-Analysis and Systematic Analyses of Safety Data

Brenda Crowe, PhD
Senior Research Advisor, Global Statistical Sciences
Eli Lilly and Company

Topic #5 – Role of Patient Preferences in Benefit-Risk Discussions

Patricia Furlong, BSN
Founding President and CEO
Parent Project Muscular Dystrophy

Topic #6 – Predictive Safety Tools

Keith K. Burkhart, MD
Senior Advisor for Medical Toxicology, Office of Clinical Pharmacology
CDER, FDA

1:30-3:00 PM

Session 7 – Benefit-Risk

Session Chair

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

In this session, we will explore various perspectives of benefit-risk within the life cycle of product development. Presentations will touch on benefit-risk framework, incorporating benefit-risk into early clinical development, and incorporating patient preferences into benefit-risk assessment.

Regulatory Perspective/Framework

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

Benefit-Risk: Quantitative/Qualitative Aspects

Lesley Wise, PhD, MSc
Vice President and Global Head PV Risk Management and Pharmacoepidemiology
Takeda Development (Europe)

Patient Perspective

Sally Okun
Vice President, Advocacy, Policy and Patient Safety
PatientsLikeMe

3:00-3:30 PM Refreshment Break and Networking in Exhibit Hall

3:30-5:00 PM

Session 8 – Customer Engagement Programs

Session Chair

Michael Richardson, MD, FFPM
International Head GPV&E and EU Qualified Person for Pharmacovigilance
Bristol-Myers Squibb

What are customer engagement programs and patient support programs (PSPs)? This session will examine key elements of these programs and how they can add value and support pharmacovigilance practices. Presenters will explore the operational challenges of setting up PSPs and managing safety information from these programs and one of the speakers will share a survey on industry best practices, regarding customer engagement programs and pharmacovigilance.

What are PSPs and Why Do We Do Them?

Coleman Gerstner
Director, Global Patient Support Program Strategy and Capabilities
Eli Lilly and Company

Customer Engagement Programs: Survey on Industry Practices Regarding Pharmacovigilance

Jamie Portnoff
Managing Consultant
Foresight Group International

Patient Support Programs - The Industry View

Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence
AbbVie Ltd.

5:00 PM End of Day Two

WEDNESDAY, JANUARY 27, 2016

7:30 AM-3:00 PM Attendee Registration

7:30-8:30 AM Continental Breakfast in Exhibit Hall

8:30-10:00 AM

Session 9 – Biosimilars

Session Chair

Mariette Boerstoel-Streefland, MD, MBA, MS
VP, Head Global Drug Safety
Baxalta

There is increasing attention for management of safety information and safety profiles for biosimilar products. Thoughts are evolving, but main issues remain how to distinguish between products and how similar/dissimilar biosimilars really are from a safety perspective.

In this session, we will explore new thinking and updates on biosimilars. FDA speakers will present on the basics of biosimilars and the scientific approach to demonstrating biosimilarity. Immunogenicity and other safety aspects, as well as naming conventions for biosimilars will also be discussed. Lastly, an industry perspective on issues and specific safety concerns with biosimilar studies will be presented.

Biosimilars 101

Leah Christl, PhD
Associate Director for Therapeutic Biologics, Office of New Drugs
CDER, FDA

Naming Conventions of Biosimilars

Kellie Taylor, PharmD, MPH
Deputy Director, Office of Surveillance and Epidemiology, CDER, FDA

Issues and Pharmacovigilance Concerns With Biosimilar Studies

Jaclyn L. F. Bosco, PhD, MPH
Director, Epidemiology and Outcomes Research
Real-World & Late Phase Research
Quintiles Inc.

10:00-10:30 AM Refreshment Break and Networking in Exhibit Hall

10:30 AM-12:00 PM

Session 10 – Advanced Therapies

Session Co-Chairs

POLLING: Use the DIA App

Robert L. Levin, MD
Director, Division of Pharmacovigilance-I
Office of Surveillance and Epidemiology
CDER, FDA

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

Gene therapy, somatic cell therapy, and tissue engineering products represent innovative therapies with the promise of expanded treatment choices for diseases where few options exist today. To promote timely access to these advanced therapies while safeguarding the public health, informed benefit-risk decisions must be made while long-term data on both safety and efficacy are developed. In this session, regulatory and industry representatives will discuss the current rationale for clinical safety considerations in the step-wise development of advanced therapies.

Overview of Advanced Therapies

Don A. Gabriel, MD, PhD
Division of Hematology
University of North Carolina

Gene Therapy: Its Promise and the Safety Issues Associated With It

Barbara Morollo
Senior Director, Pharmacoviligance
bluebird bio, Inc.

Uncertainty and Issues Surrounding Biomedical Innovation

Kenneth Oye, PhD
Associate Professor, Political Science; Co-Director, Program on Emerging Technologies
Massachusetts Institute of Technology (MIT)

12:00-1:30 PM Luncheon in Exhibit Hall

1:30-3:00 PM

Session 11 – HOT TOPIC PANEL: Earlier Access vs. Additional Safety?

POLLING: Use the DIA App

Session Co-Chairs

LCDR Dipti Kalra, RPh
Safety Evaluator, Division of Pharmacovigilance-I
Office of Surveillance and Epidemiology
CDER, FDA

Annette Stemhagen, DrPH
Senior Vice President
Safety, Epidemiology, Registries and Risk Management
UBC, An Express Scripts Company

Patients need faster access to innovative, effective, and safe medicines, especially in cases where there are no adequate treatments available. In 2012, the FDA introduced a new regulatory pathway called Breakthrough Therapy Designation, which aims to accelerate the development and review of drugs to treat serious or life-threatening conditions. The EMA Adaptive Pathways pilot is part of efforts to get patients suffering from serious conditions with an unmet medical need faster access to new drugs. Meanwhile, other regulators around the world are also exploring the adaptive licensing model (e.g. Singapore's HSA, Health Canada). One critical question in accelerating the approval process is how much safety data is needed before breakthrough therapies can be approved. This session will explore this issue from multiple perspectives in a Q&A panel discussion format.

Panelists

Submit your questions for the panel at the DIA registration desk.

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

Patricia Furlong, BSN
Founding President and CEO
Parent Project Muscular Dystrophy

Don A. Gabriel, MD, PhD
Division of Hematology
University of North Carolina

Heidi Gertner, JD
Partner
Hogan Lovells US LLP

Joanna Faith Haas, MD, MSc
Founding Partner
Haas and Partners LLC

3:00 PM **Conference Adjourns**

Exhibiting Companies

- APCER Life Sciences
- ArisGlobal, LLC
- Ashfield Pharmacovigilance
- C3i Healthcare Connections
- Doctor Evidence
- Dohmen Life Science Services
- Drug Safety Navigator, LLC
- Foresight Group International AG
- Gilead Sciences, Inc.
- Juno Therapeutics
- Language Scientific, Inc.
- Medical Vigilance Solutions
- MyMeds&Me
- November Research Group
- PleaseTech Ltd.
- PPD
- ProPharma Group
- Quintiles
- RxLogix
- Sciformix Corporation
- Symogen Limited
- UBC
- Uppsala Monitoring Centre
- Vigilare International

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>
> – Barbara Lopez Kunz, DIA Global Chief Executive

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