Pharmacovigilance and Risk Management Strategies 2015

Tutorials: January 25 | Meeting: January 26-28

Renaissance Washington DC Downtown Hotel
Washington, DC

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., United Kingdom

PROGRAM COMMITTEE:

Mariette Boerstoel-Streefland, MD, MBA, MS
Head
Global Safety and Pharmacovigilance
Baxter International Inc.

Jean-Pierre Clement, MD
Vice President
Global PV and Medical Risk Management
Cubist Pharmaceuticals, Inc.

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

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

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

Tracy M. Salaam, PharmD
Safety Evaluator Team Leader
CDER, FDA

DEVELOP.
INNOVATE. ADVANCE.

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

DIAGlobal.org

OVERVIEW

Benefit-Risk in 2015! Regulatory science, tools, realities, and perceptions of biopharmaceutical product benefit-risk continue to evolve across the global pharmacovigilance landscape. During this three-day meeting, thought leaders from around the world will provide their insight and engage in dialogue on current opportunities and challenges in managing product risk in the context of benefit. The current regulatory framework will be outlined and practical approaches to protecting patient safety will be discussed.

This event will provide a unique setting for informal dialogue with representatives from the FDA and other key regulatory agencies, as well as from industry and academia. There will be multiple opportunities for participants to engage with speakers and interact with fellow colleagues.

LEARNING OBJECTIVES

At the conclusion of this meeting, attendees will be able to:

- Describe the current regulatory framework for pharmacovigilance in key markets
- Discuss global implications of the Pharmacovigilance System Master File
- Explain basic risk minimization interventions, measures of their effectiveness, and integration into selected healthcare systems
- Describe new approaches for safety assessment of biosimilars in early clinical development
- Examine the role of Real World Evidence in assessing product risk in the context of benefit
- Discuss the impact of health literacy on risk communication

DIA DEVELOP INNOVATE ADVANCE

800 Enterprise Road
Suite 200
Horsham, PA 19044 USA

DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing, China
Horsham, PA, USA | Mumbai, India | Tokyo, Japan

CONTINUING EDUCATION CREDITS

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 (1.175 CEUs) and applicable tutorial (.6 CEUs) are designated for up to 17.75 contact hours or 1.775 continuing education units (CEU's). See Continuing Education Credit Allocation below for details.

Type of Activity: Knowledge

ACPE Credit Requests
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.
ALL ACPE CREDIT REQUESTS MUST BE SUBMITTED THROUGH DIA'S MY TRANSCRIPT BY FRIDAY, MARCH 13, 2015.

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 up to 2.3 CEUs (.3 CEUs for half day tutorials; .6 CEUs for full day tutorial; 1.7 CEUs for the meeting) program. Participants must attend the entire program <and tutorial(s), if applicable> in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the program <and tutorial, if applicable>, sign in at the DIA registration desk each day of the meeting, and complete the online credit request process through My Transcript. To access My Transcript, please go to www.DIAGlobal.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. 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 on **Wednesday, February 11, 2015**.

Disclosure Policy
The Postgraduate Institute for Medicine (PIM) and DIA require instructors, planners, managers and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by PIM and DIA for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations.

Grievance Policy
It is DIA's policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest 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. Faculty disclosures will be included in the workshop materials. View DIA's Grievance Policy at **DIAGlobal.org/CE**

CONTINUING EDUCATION CREDIT ALLOCATION

Tutorials:
- **Pharmacovigilance and Risk Management Planning:** Pharmacy: 6 contact hours or .6 CEUs, 0286-0000-15-005-L04-P; Nursing: 6 contact hours; IACET: .6 CEUs
- **Introduction to Pharmacoepidemiology and Applications in PreMarketing and PostMarketing Surveillance, Risk Management and Value Demonstration:** Nursing: 3.25 contact hours; IACET: .3 CEUs
- **PBRERs:** Nursing: 3.25 contact hours; IACET: .3 CEUs
- **Pharmacovigilance System Master File:** Nursing: 3.25 contact hours; IACET: .3 CEUs

Meeting:
CME: 16.5 *AMA PRA Category 1 Credits™*
Nursing: 16.5 contact hours
IACET: 1.7 CEUs

Pharmacy:
- **Session 1 - Keynote Address:** 1.25 contact hours or .125 CEUs, 0286-0000-15-006-L04-P
- **Session 2 – FDA Updates:** 1.5 contact hours or .15 CEUs, 0286-0000-15-007-L04-P
- **Session 6 – Regional Requirements with Global Impact: The Drivers for Change:** 1.5 contact hours or .15 CEUs, 0286-0000-15-008-L04-P
- **Session 7 – Risk Management Planning:** 1.5 contact hours or .15 CEUs, 0286-0000-15-009-L04-P
- **Session 8 – Implementing Additional Risk Minimization Tools and Measuring Their Effectiveness:** 1.5 contact hours or .15 CEUs, 0286-0000-15-010-L04-P
- **Session 9 – Enhancing Pharmacovigilance Engagement….:** 1.5 contact hours or .15 CEUs, 0286-0000-15-011-L04-P
- **Session 10 – Real World Evidence….:** 1.5 contact hours or .15 CEUs, 0286-0000-15-012-L04-P
- **Session 11 – Stakeholder Perspectives on Communicating Risk:** 1.5 contact hours or .15 CEUs, 0286-0000-15-013-L04-P

DIA'S CERTIFICATE PROGRAM

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

- Clinical Research Certificate Program: 12 Elective Units
- Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
- Regulatory Affairs Certificate Program: 12 Elective Units

For more information go to **www.DIAGlobal.org/CertificatePrograms**

TO ACCESS PRESENTATIONS:

- Visit **DIAGlobal.org**
- Login to My DIA
- Enter your User ID and Password
- View 'My Presentation Downloads'

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

SUNDAY, JANUARY 25

FULL-DAY TUTORIAL

10:00AM–5:00PM **PHARMACOVIGILANCE AND RISK MANAGEMENT PLANNING (box lunch served from 12:00-12:45PM)**

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., United Kingdom

This tutorial will be presented in two parts.

Part 1 (10:00AM–12:00PM) will focus on basic aspects of the regulatory framework for pharmacovigilance in the context of risk management planning.

Part 2 (12:45–5:00PM) will focus on the practical aspects of managing biopharmaceutical product risks in the context of benefits and the healthcare delivery system.

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 tools for managing product risks, how the effectiveness of a selected tool is assessed, and triggers for modification or release of a given intervention

HALF-DAY TUTORIALS

8:30AM-12:00PM **INTRODUCTION TO PHARMACOEPIDEMIOLOGY AND APPLICATIONS IN PREMARKETING AND POSTMARKETING SURVEILLANCE, RISK MANAGEMENT AND VALUE DEMONSTRATION**

INSTRUCTORS

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

Robert Sharrar, MD
Executive Director
Safety, Epidemiology, Registries and Risk Management
UBC, An Express Scripts Company

This tutorial will provide an overview of basic epidemiology methods and study designs as they are applied in the pharmaceutical and biotechnology industries. Topics will include design and conduct of retrospective and prospective epidemiologic studies such as case-control studies and cohort studies, and the application of these designs for premarketing and postmarketing surveillance, risk management (risk assessment and risk mitigation), and demonstration of product value.

Learning Objectives:

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

- Define basic epidemiologic principles
- Distinguish case-control and cohort study designs
- Identify applications for epidemiology in pre- and postmarketing pharmaceutical product safety surveillance and risk management
- Identify applications for use of epidemiologic studies in demonstrating product value

Lunch is not provided for half-day tutorial attendees

1:30-5:00PM PBRERS

INSTRUCTORS

Valerie E. Simmons, MD, FFPM
EU Qualified Person for Pharmacovigilance
Global Patient Safety
Eli Lilly and Company Limited
United Kingdom

Ayman Ayoub, MD
Disease Area Head
Safety Surveillance and Risk Management
Pfizer LTD Central Research
United Kingdom

Alison Turney, PharmD
Consultant
Surveillance Process Owner
Eli Lilly and Company

The new ICH E2C (E2C) guideline on Periodic Benefit-Risk Evaluation Reports (PBRERs) reached Step 4 in November 2012 and has already implemented in the EU under the new Pharmacovigilance legislation. Also accepted in the US, Japan, and other countries, the PBRER may replace existing requirements for postmarketing periodic reporting. This new report represents a significant change from the previous PSUR format and a quantum leap forward towards a document incorporating 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 the practical aspects in the preparation of the PBRER

1:30-5:00PM PHARMACOVIGILANCE SYSTEM MASTER FILE

INSTRUCTOR

Noha Kassem, PhD
Senior Director
Quality in Global Patient Safety
Eli Lilly and Company
United Kingdom

As part of the new EU Pharmacovigilance Legislation (Regulation EU 1235/2010 and Directive 2010/84/EU) marketing-authorization holders are required to maintain a Pharmacovigilance System Master File (PSMF). The PSMF must be in place at the time of initial marketing authorization application, license renewal and available for inspections. The PSMF replaced the Detailed Description of the Pharmacovigilance System (DDPS). This tutorial will cover the requirements in the PSMF, the creation and maintenance as well as sharing a real experience focusing on some of challenges and how they can be addressed.

Learning Objectives:

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

- Discuss how to prepare a PSMF to meet the requirements
- Describe how to maintain a PSMF so that it can be available within seven days from request
- Examine challenges and possible scenarios of how to address preparation and maintenance

MONDAY, JANUARY 26

7:30-8:30AM REGISTRATION / CONTINENTAL BREAKFAST / EXHIBITS

8:30-8:45AM DIA WELCOME AND OPENING REMARKS

DIA WELCOME

Barbara Lopez Kunz
Global Chief Executive
DIA

PROGRAM CHAIR

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

PROGRAM CO-CHAIR

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

8:45-10:00AM 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., United Kingdom

Do Meta-analyses of Adverse Events have Adverse Effects?

Stephen JW Evans, MSc, FRCP
Professor of Pharmacoepidemiology
London School of Hygene & Tropical Medicine
United Kingdom

10:00-10:30AM REFRESHMENT BREAK / EXHIBITS

10:30AM-12:00PM SESSION 2: FDA UPDATES

SESSION CHAIR:

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

SPEAKERS:

Updates from the FDA/Office of Surveillance and Epidemiology

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

Using Drug Target Adverse Event Profiles to Predict and Analyze Safety Signals

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

Pharmacological Mechanism-Based Approaches for Signal Strengthening/Weakening for Potential Safety Signals

Darrell R. Abernethy, MD, PhD
Associate Director for Drug Safety
Office of Clinical Pharmacology
CDER, FDA

12:00-1:30PM ROUNDTABLE LUNCH DISCUSSIONS/EXHIBITS

New This Year!

There will be a 30 minutes session for a limited number of participants to join roundtable discussions during the lunch break. The discussions will address the following topics:

- Informatic Approaches to Data Mine FAERS for Mechanisms of Toxicity - Moderated by **Keith K. Burkhart, MD, FACMT**, Senior Advisor for Medical Toxicology, Office of Clinical Pharmacology, CDER, FDA
- Systems Pharmacology and Toxicology - International Efforts to Develop Mechanistic Approaches to Inform Potential Pharmacoepidemiologic Safety Signals - Moderated by **Darrell R. Abernethy, MD, PhD**, Associate Director for Drug Safety, Office of Clinical Pharmacology, CDER, FDA
- Regulatory decision-making: are we getting it right? - Moderated by **Stephen JW Evans, MSc, FRCP,** Professor of Pharmacoepidemiology, London School of Hygene & Tropical Medicine, United Kingdom

An email will be sent to all pre-registered attendees with instructions for how to sign up for a Round Table. It is first come, first serve and will be closed once the slots are filled. Please monitor email for this sign up opportunity.

1:30-3:00PM SESSION 3: ASIA REGULATORY UPDATES

SESSION CHAIR:

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

SPEAKERS:

Japanese Perspective

Daisuke Sato, MPharm
Reviewer
Office of Safety II
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Korea Perspective

Nam-Kyong Choi, PhD
Research Professor
Division of Clinical Epidemiology
Seoul National University College of Medicine/Seoul National University Hospital

Pre- and Post-Marketing Safety Evaluation in China

William Wang, PhD
Head of Asia Pacific Hub
Biostatistics and Research Decision Sciences (BARDS)
Merck Research Laboratories, Merck & Co., Inc., China

3:00-3:30PM REFRESHMENT BREAK / EXHIBITS

3:30-5:00PM **SESSION 4: MATURING MARKETS PERSPECTIVE**

SESSION CHAIR:

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

SPEAKERS:

India Perspective

Brijesh Regal, MPharm
CEO
Apothecaries Clinical Research, India

Brazil Perspective

Paula Taborelli
Regional Director Pharmacovigilance (EU & LA)
Global PhV & Epidemiology
Bristol-Myers Squibb

Eastern Europe/Turkey Perspective

Michelle Bulliard
Vice President, Regional Managing Director EMEA
Quintiles Switzerland

5:00-6:00PM **NETWORKING RECEPTION**

TUESDAY, JANUARY 27

7:30-8:30AM **REGISTRATION / CONTINENTAL BREAKFAST / EXHIBITS**

8:30–10:00AM **SESSION 5: EU REGULATORY UPDATES**

SESSION CHAIR:

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

SPEAKERS:

A Very Personal Perspective on PRAC (Pharmacovigilance and Risk Assessment Committee)

Stephen JW Evans, MSc, FRCP
Professor of Pharmacoepidemiology
London School of Hygene & Tropical Medicine
United Kingdom

Success and Future Challenges of New Regulations

Mick Foy
Group Manager
Vigilance Intelligence and Research Group
MHRA, United Kingdom

Success and Future Challenges of New Regulations – Industry Perspective

Vicki Edwards, BPHARM HONS
QPPV and Head of Affiliate Vigilance Excellence
Pharmacovigilance and Patient Safety
AbbVie Ltd, United Kingdom

10:00-10:30AM **REFRESHMENT BREAK / EXHIBITS**

10:30AM-12:00PM **SESSION 6: REGIONAL REQUIREMENTS WITH GLOBAL IMPACT: THE DRIVERS FOR CHANGE**

SESSION CHAIRS:

Justina Molzon, JD, MPharm, MSc, RPh
CDER, FDA (Retired)

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

SPEAKERS:

FDA Perspective on International Regulatory Collaborations in Pharmacovigilance

Robert Ball, MD, MPH, ScM
Deputy Director, Office of Surveillance and Epidemiology
CDER, FDA

Pharmacovigilance System Master File

Noha Kassem, PhD
Senior Director
Quality in Global Patient Safety
Eli Lilly and Company, United Kingdom

A View of APEC

Justina Molzon, JD, MPharm, MSc, RPh
CDER, FDA (Retired)

Global Database and Accommodating Differing Reporting Requirements and Safety Analysis

Eileen Leonard, PharmD
Executive Director
Global Pharmacovigilance and Epidemiology
Bristol-Myers Squibb

12:00-1:30PM **LUNCH / EXHIBITS**

1:30-3:00PM **SESSION 7: RISK MANAGEMENT PLANNING**

SESSION CHAIR:

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

SPEAKERS:

ADRs, Risks, What is Important...and Can Anyone Tell the Difference Anymore?

Valerie E. Simmons, MD, FFPM
EU Qualified Person for Pharmacovigilance
Global Patient Safety
Eli Lilly and Company Limited, United Kingdom

Practical Considerations on Implementing the Pharmacovigilance Plan: Planning Multi-Country PASS

Michelle Bulliard
Vice President, Regional Managing Director EMEA
Quintiles, United Kingdom

Different Strategies for Risk Minimisation in the EU

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

3:00-3:30PM **REFRESHMENT BREAK / EXHIBITS**

3:30-5:00PM **SESSION 8: IMPLEMENTING ADDITIONAL RISK MINIMIZATION TOOLS AND MEASURING THEIR EFFECTIVENESS**

ESSION 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., United Kingdom

SPEAKERS:

Risk Minimization – Tools to Measure Effectiveness

Cynthia LaCivita, PharmD
Senior Drug Risk Management Analyst
Division of Risk Management
Office of Medication Error Prevention and Risk Management
CDER, FDA

Case Study

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

Future Direction: CIOMS IX

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

WEDNESDAY, JANUARY 28

7:30-8:30AM **REGISTRATION / CONTINENTAL BREAKFAST / EXHIBITS**

8:30-10:00AM SESSION 9: ENHANCING PHARMACOVIGILANCE ENGAGEMENT IN THE CLINICAL DEVELOPMENT OF LARGE MOLECULES

SESSION CHAIR:

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

SPEAKERS:

The Clinical Relevance of Quality

Steven Kozlowski, MD
Director
Office of Biotechnology Products
CDER, FDA

Establishing Biosimilarity through Assessment and Comparison of Critical Quality Attributes

Jan Hillson, MD
Senior Director of Clinical and Translational Research
Momenta Pharmaceuticals, Inc.

Pharmacovigilance: Considerations for Biologics and Biosimilars

Thomas Felix, MD
Director, Research and Development Policy
Amgen Inc.

10:30AM-12:00PM SESSION 10: REAL WORLD EVIDENCE - A TRUE SNAPSHOT OF BENEFIT AND RISK

SESSION CHAIR:

Mariette Boerstoel-Streefland, MD, MBA, MS
Head
Global Safety and Pharmacovigilance
Baxter International Inc.

SPEAKERS:

Exploring New Methods for Pharmacovigilance

Nancy Dreyer, PhD, MPA, FISPE
Global Chief of Scientific Affairs
Quintiles Real-World & Late-Phase Research
Adjunct Professor of Epidemiology
University of North Carolina

Anonymized Datasets from Multiple Organizations: Potential for Use in Epidemiology and Signal Detection

Andres Gomez
Head of Epidemiology, Signal Detection and Data Management
Bristol Myers Squibb

Benefits and Harms of "Real World" Evidence: Should We Be Changing Our Views?

Stephen JW Evans, MSc, FRCP
Professor of Pharmacoepidemiology
London School of Hygene & Tropical Medicine
United Kingdom

12:00-1:30PM **LUNCH / EXHIBITS**

1:30-3:00PM **SESSION 11: STAKEHOLDER PERSPECTIVES ON COMMUNICATING RISK**

SESSION CHAIR:

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

SPEAKERS:

Patient Perspective

Toni Cordell
Consultant
Toni Cordell

MHRA Perspective

Mick Foy
Group Manager
Vigilance Intelligence and Research Group
MHRA, United Kingdom

Risk Communication and Health Literacy in Healthcare Systems

Professor Michael Wolf, PhD, MPH
Professor
Medicine-General Internal Medicine and Geriatrics
Northwestern University Feinberg School of Medicine

3:00PM **MEETING ADJOURNS**