Pharmacovigilance and Risk Management Strategies 2014

Tutorials: January 12 | Meeting: January 13-15
Washington, DC

PROGRAM CO-CHAIRS:

JP Clement, MD
Vice President
Drug Safety and Pharmacovigilance
Onyx Pharmaceuticals Inc.

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

PROGRAM COMMITTEE:

Mariette Boerstoel-Streefland, MD, MBA, MS
Chief Safety Officer, Vice President-Global Drug Safety
Forest Research Institute

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Vice President, Chief Medical Officer, Director
Corporate Medical Affairs HQ
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Stephen Knowles, MD, MRCP
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International Head GPV&E and EU Qualified Person for Pharmacovigilance
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Current Complexities and Controversies in Pharmacovigilance, Signal, and Risk Management

OVERVIEW:

This global three-day meeting will provide new insights into the current issues and associated challenges impacting drug safety, focusing primarily on drug products and biologics, throughout all phases of development and marketed use. Top pharmaceutical, biotechnology, and regulatory thought leaders convene each January to discuss new and updated legislation in various ICH regions, current regulatory framework for pharmacovigilance in global regions, operational challenges of implementing global Benefit-risk analyses and risk management plans, the impact of social media, and the role of epidemiology in safety analysis.

LEARNING OBJECTIVES:

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

- Describe the current global regulatory framework for pharmacovigilance and the move toward harmonization
- Describe operational challenges of implementing global Benefit-risk analyses and risk management plans
- Discuss how information technologies and social media are impacting pharmacovigilance
- Examine the role of epidemiology in safety analysis

TUTORIAL TOPICS:

- Pharmacovigilance and Risk Management Planning
- Introduction to Pharmacoepidemiology and Applications in Premarketing and Postmarketing Surveillance, Risk Management, And Value Demonstration
- Pharmacovigilance System Master File
- ICH E2C (R2): The Quantum Leap from PSURs to Benefit-Risk Evaluation (PBRERs)

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CONTINUING EDUCATION

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. 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 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program and applicable tutorial are designated for up to 10.5 contact hours or 1.05 continuing education units (CEU's).

Type of Activity: Knowledge

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CONTINUING EDUCATION CREDIT ALLOCATION

Tutorials:

Tutorial #1: Pharmacovigilance and Risk Management Planning: Pharmacy: 3.25 contact hours or .325 CEUs, 0286-0000-14-019-L04-P; Nursing: 3.25 contact hours; IACET: .3 CEUs

Tutorial #2: Introduction to Pharmacoepidemiology and Applications in Premarketing and Postmarketing Surveillance, Risk Management and Value Demonstration: Nursing: 3.25 contact hours; IACET: .3 CEUs

Tutorial #3: ICH E2C (R2); The Quantum Leap from PSURs to Benefit-Risk Evaluation (PBRERs): Nursing: 3.25 contact hours; IACET: .3 CEUs

Tutorial #4: Pharmacovigilance System Master File: Nursing: 3.25 contact hours; IACET: .3 CEUs

Meeting:
CME: 16.5 AMA PRA Category 1 Credit(s)TM
Nursing: 16.5 contact hours
IACET: 1.7 CEUs
Pharmacy:

- **Session 1 - Keynote Presentation: Digital Disease Detection:** 1.25 contact hours or .125 CEUs, 0286-0000-14-020-L04-P
- **Session 7 – Benefit-Risk and Risk Management:** 1.5 contact hours or .15 CEUs, 0286-0000-14-021-L04-P
- **Session 8 – Patient Perspective:** 1.5 contact hour or .15 CEUs, 0286-0000-14-022-L04-P
- **Session 9, Part II – Real World Evidence: Safety Applications:** 1.5 contact hours or .15 CEUs, 0286-0000-14-023-L04-P
- **Session 10 – Social Media:** 1.5 contact hours or .15 CEUs, 0286-0000-14-024-L04-P

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

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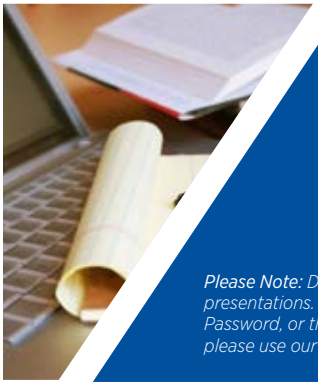

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TUTORIALS | SUNDAY, JANUARY 12

8:30AM-12:00PM AM TUTORIALS

Tutorial #1 – Pharmacovigilance and Risk Management Planning

Tutorial Instructor

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

This tutorial will focus on the practical aspects of managing biopharmaceutical product risks in the context of a product's benefits.

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
- 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 removal of a given intervention

Tutorial #2 – Introduction to Pharmacoepidemiology and Applications in Premarketing and Postmarketing Surveillance, Risk Management, and Value Demonstration

Tutorial Instructors

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

Robert Sharrar, MD
Executive Director
Safety, Epidemiology, Registries and Risk Management
United BioSource Corporation

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

1:30-5:00PM PM TUTORIALS

Tutorial #3 – ICH E2C (R2): The Quantum Leap from PSURs to Benefit-Risk Evaluation (PBRERs)

Tutorial 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

Tutorial #4 - Pharmacovigilance System Master File (PSMF)

Tutorial 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 13

7:30-8:30AM CONTINENTAL BREAKFAST AND ATTENDEE REGISTRATION

8:30–8:45AM WELCOME AND OPENING REMARKS

Program Co-chairs

JP Clement, MD
Vice President
Drug Safety and Pharmacovigilance
Onyx Pharmaceuticals, Inc.

William W. Gregory
Senior Director
Safety and Risk Management
Pfizer Inc.

8:45-10:00AM SESSION 1

Keynote Presentation

Session Co-chairs

JP Clement, MD
Vice President
Drug Safety and Pharmacovigilance
Onyx Pharmaceuticals, Inc.

William W. Gregory
Senior Director
Safety and Risk Management
Pfizer Inc.

Digital Disease Detection

John Brownstein, PhD
Manager and Associate Professor
Boston Children's Hospital and Harvard Medical School

10:00-10:30AM REFRESHMENT BREAK

10:30AM-12:00PM SESSION 2

FDA Updates

Session Chair

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

Regulatory Updates from the FDA

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

Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data

Judy Staffa, MD, PhD
Director
OSE Division of Epidemiology
CDER, FDA

12:00-1:30PM LUNCH

1:30-3:00PM SESSION 3

Drug Safety in China – The Importance of What's Happening

Session Chair

Stewart Geary, MD
Vice President, Deputy Director
Eisai Co., Ltd., Japan

Pharmacovigilance in China: The Current Landscape

Vera Liang
Global Safety Risk Lead and Director
Safety Surveillance and Risk Management
Pfizer R&D Co., Ltd., China

CRO Perspective

Deirdre McCarthy, MSc
Director
Integrated Post-marketing and QPPV Services
Customer Safety Services
Quintiles

Industry Perspective

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

3:00-3:30PM REFRESHMENT BREAK

3:30-5:00PM SESSION 4

Emerging Markets

Session Chair

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

Japanese Perspective

Yoshinori Takeuchi, DVM, PhD, MPH
Pharmacoepidemiologist
Surveillance and Analysis Division, Office of Safety I
Pharmaceuticals and Medical Devices Agency (PMDA)

Latin America Perspective

Marisa Fernandes, BSN, RN
Manager
Drug Safety Center, Latin America
PRA International

India Perspective

Moin Don
Executive Director and Founder
PVCON Pharmacovigilance Consulting Services

5:00-6:00PM NETWORKING RECEPTION

TUESDAY, JANUARY 14

7:30-8:30AM CONTINENTAL BREAKFAST AND ATTENDEE REGISTRATION

8:30-10:00AM SESSION 5

EU Regulations – Regulatory Overview

Session Co-chairs

Vicki Edwards
Qualified Person for Pharmacovigilance and
Head of Affiliate Vigilance Excellence
Abbvie Ltd.

Almath Spooner
Lead, Pharmacovigilance and Risk Management
IMB and Vice Chair, PRAC
Irish Medicines Board

Regulatory Overview

Mick Foy
Group Manager
Vigilance Intelligence and Research Group
MHRA

PRAC Perspective

Almath Spooner
Lead
Pharmacovigilance and Risk Management
IMB and Vice Chair, PRAC
Irish Medicines Board

Industry Perspective

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

Panel Discussion

10:00-10:30AM REFRESHMENT BREAK

10:30AM-12:00PM SESSION 6

Harmonization

Session Chair

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

US Perspective

Justina Molzon, JD, MPharm
Associate Center Director for International Programs
CDER, FDA

Asian Perspective

Stewart Geary, MD
Vice President, Deputy Director
Eisai Co., Ltd.
Japan

European Perspective

Moira Daniels, MBA
Vice President, Head Global Patient Safety Services, PACE
PAREXEL International
United Kingdom

Legal Perspective

Richard F. Kingham, Esq.
Partner
Covington & Burling

12:00-1:30PM LUNCH

1:30-3:00PM SESSION 7

Benefit-Risk and Risk Management

Session Co-chairs

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

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

Benefit-Risk in Relation to Risk Management

Susan Welsh
Vice President
Medical Safety
Bristol-Myers Squibb

Benefit-Risk Work Streams: Quantitative vs. Qualitative

Rebecca A. Noel
Senior Research Scientist
Global Patient Safety
Eli Lilly and Company

Benefit-Risk from a Regulator's Perspective

Sara Eggers
Operations Research Analyst
Office of Program and Strategic Analysis
CDER, FDA

3:00-3:30PM REFRESHMENT BREAK

3:30-5:00PM SESSION 8

Patient Perspective

Session Chair

Peg Fletcher, MD, PhD
President
MedAssessment Inc.

Speakers

Eric Gascho
Director, Government Affairs
National Health Council

Diane D. Edquist Dorman
Vice President, Public Policy
National Organization For Rare Disorders (NORD)

5:00PM END OF DAY 2

WEDNESDAY, JANUARY 15

7:30-8:30AM CONTINENTAL BREAKFAST AND ATTENDEE REGISTRATION

8:30-10:00AM SESSION 9 – PART I

Real World Evidence: The Building Blocks

Session Chair

Mariette Boerstoel-Streefland, MD, MBA, MS(epi)
Chief Safety Officer, Vice President
Global Drug Safety
Forest Research Institute, a Subsidiary of Forest Laboratories Inc.

PROTECT

Robert Reynolds
Vice President, Global Head, Epidemiology
Pfizer Inc

Sentinel Updates

Katrina Mott, MHS
ORISE Fellow
CDER Sentinel Team
CDER, FDA

Partnerships Between Pharma and Database Owners

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

10:00-10:30AM REFRESHMENT BREAK

10:30-12:00PM SESSION 9 – PART II

Real World Evidence: Safety Applications

Session Chair

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

Current Use of Real World Evidence of Signal Assessment

John D. Seeger, PharmD, DrPh
Assistant Professor
Harvard Medical School/Brigham & Women's Hospital

Future of Large Databases in Data Mining

Andrew Bate
Senior Director, Analytics Team Lead
Epidemiologist, Worldwide Safety Strategy
Pfizer Inc

Assessing the Effectiveness of Risk Minimization Programs: Future Needs and Opportunities for Using Real World Evidence

Gary H. Slatko, MD
Director
Office of Medication Error Prevention and Risk Management, OSE
CDER, FDA

12:00-1:30PM LUNCH

1:30-3:00PM SESSION 10

Social Media

Session Co-chairs

Elizabeth E. Garrard, PharmD
Senior Director
Safety Risk Management
United Therapeutics Corporation

Linda J. Scarazzini, MD
Vice President
Medical Safety Evaluation
AbbVie

FDA Perspective

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

Upstream Activities

Andrew R. Rut, MD
CEO
My Meds & Me

Safety & Social Media

Nabarun Dasgupta, MPH, PhD
Professor, University of North Carolina at Chapel Hill
Scientist, Epidemico

3:00PM MEETING ADJOURNS