

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 Boerstoele-Streefland, MD, MBA, MS

Chief Safety Officer, Vice President-Global Drug Safety
Forest Research Institute

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

Register by December 23 to Save!

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)

Register at
diahome.org/Safety2014

DIA WORLDWIDE HEADQUARTERS

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CONTINUING EDUCATION



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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)[™]

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

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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 INSTRUCTOR

Annette Stenhagen, DrPH, FISPE

Senior Vice President
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 INSTRUCTOR

Valerie E. Simmons, MD, FFPM

EU Qualified Person for Pharmacovigilance
Global Patient Safety
Eli Lilly and Company Limited
United Kingdom

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-authorisation 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

Individual Case Reporting: DSURs vs. IND Annual Reports

FDA Representative Invited

Regulatory Updates from the FDA

Gerald J. Dal Pan

Director
Office of Surveillance and 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

Development Safety

Speaker Invited

Postmarketing Safety

Speaker Invited

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

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

FDA Speaker Invited

Asian Perspective

Stewart Geary, MD

Vice President, Deputy Director
Eisai Co., Ltd.
Japan

European Perspective

Speaker Invited

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

FDA Speaker Invited

3:00-3:30PM REFRESHMENT BREAK

3:30-5:00PM SESSION 8

Patient Perspective

SESSION CHAIR

Peg Fletcher, MD, PhD

President
MedAssessment Inc.

SPEAKERS

Marc Boutin

Executive Vice President & Chief Operating Officer
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 Boerstoele-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

Marsha Reichman, PhD
Senior Advisor and Scientific Lead
Surveillance Programs
CDER Sentinel Initiative Lead
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



Benefit-Risk Assessment from Inception to Maturation: Aligning Regulatory and Industry Goals

Tutorial: February 9 | Meeting: February 10-11 | Bethesda, MD
Register by January 21 to Save!

Join FDA, EMA, Health Canada, and other regulatory agencies, patient, industry, and academic representatives to discuss the progress and application of Benefit-risk assessment throughout the development and post-approval life cycle. You will learn processes and methods that help enhance sponsor and regulatory decision-making.

Register at diahome.org/Benefitrisk



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

Head
Medical Safety Evaluation
AbbVie

FDA Perspective

FDA Speaker Invited

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

DIA 2014

50th Annual Meeting

June 15-19 | San Diego, CA

'Celebrate the Past - Invent the Future'

This year marks the 50th Anniversary of the DIA Annual Meeting, the largest multidisciplinary event that brings together a global network of life sciences professionals to foster innovation that will lead to the development of safe and effective medical products and therapies to patients. Come celebrate with us in San Diego this June!

Program Co-chairs:

Rear Adm. (ret) Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs
CDER, FDA



Freda C. Lewis-Hall, MD, FAPA
Chief Medical Officer and Executive
Vice President, Pfizer Inc.



Register at diahome.org/DIA2014

