Pharmacovigilance and Risk Management Strategies 2015

Tutorials: January 25 | Meeting: January 26-28
Renaissance Washington DC Downtown Hotel
Washington, DC

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
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 (1.75 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.

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; 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
- PBRETs: 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: 17 CEUs

Pharmacy:
- Session 1 - Keynote Address: 1.25 contact hours or .125 CEUs; 0286-0000-15-006-L04-P
- Session 2 - FDA Update: 1.5 contact hours or .15 CEUs; 0286-0000-15-007-L04-P
- Session 5 – 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

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### 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*
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

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 Hygiene & 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

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12:00-1:30 PM  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

1:30-3:00 PM  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

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

Drug Safety:
Is Your Staff Prepared?

DIA’s Drug Safety eLearning Program is Your Training Solution to Reduce Risk

Drug safety is a primary concern throughout the medical product development life cycle. Developed with DIA expertise to meet the unique needs of its stakeholders and members, this online safety program provides the knowledge your staff needs, from regulations and requirements through premarket review and postmarket monitoring.

Make Sure Your Staff is Ready.
Enroll today at DIAGlobal.org/SafetyeLearning or contact Katie.Hill@DIAHome.org for information on group discounts and licensing.
### 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

### 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 Hygiene & 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

### 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:**
- **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
1:30-3:00 PM  
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

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

SESSION 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 Hygiene & Tropical Medicine
United Kingdom

12:00-1:30PM  LUNCH / EXHIBITS
Keep Your Staff Ahead of the Curve with 2015 Training Courses

Art of Writing a Clinical Overview
February 24-26 | Online
Course Level: Beginner
Get an in-depth analysis of the preparation of a Clinical Overview for pharmaceutical products (drugs and biologics) in accordance with ICH guidelines concerning development of Module 2.5 of a Common Technical Document (CTD).

Introduction to Signal Detection and Data Mining
March 2 | DIA Global Center | Dupont Circle, Washington, DC
Course Level: Beginner
Experts will present techniques for beginners to uncover potential drug safety signals. Instruction will follow on the role of data mining in signal detection.

Premarketing Clinical Safety & Pharmacovigilance
March 23-24 | DIA Global Center | Dupont Circle, Washington, DC
Course Level: Intermediate
Learn how to comply with evolving US and European regulations for clinical safety during product development that are changing how we approach our daily jobs.

Advanced Signal Detection – Tools, Triage, Evaluation, and Escalation
April 20-21 | DIA Global Center | Dupont Circle, Washington, DC
Course Level: Advanced
This course will present signal detection and management in the framework of regulatory compliance as well as risk management and risk communication strategies.

Save by Sending Your Entire Team.
Register 3 Individuals and Get the 4th Free!