Find Solutions to the Challenges Facing Pharmacovigilance and Risk Management Programs

Robust drug safety systems and processes and thorough ongoing safety surveillance are more critical than ever in the development and evaluation of the safe use of marketed medicinal products.

This comprehensive three-day program will discuss the current complexities and controversies in pharmacovigilance and risk management throughout all phases of development and marketed use, how to optimally utilize epidemiological, clinical pharmacological and other techniques, risk management strategies, and how to create an effective organizational “system.”

This program will focus primarily on drug products and biologics, but medical devices will have a limited role in the discussions.

Featured Topics

• Latest international regulatory developments
• How to generate and assess critical safety data during development
• Compliance with clinical safety and post-marketing pharmacovigilance regulatory requirements in an evolving global environment
• Recent multinational initiatives under the International Conference on Harmonization (ICH) and Council for International Organizations of Medical Sciences (CIOMS) on Drug Safety Update Reports (DSURs) in premarketing clinical trial safety
• New approaches in risk management, risk communication, labeling and packaging to optimize medical product benefit while minimizing preventable harm

Who Should Attend

Professionals with at least basic knowledge of, and experience in, clinical safety and who are involved in:
• Pharmacovigilance
• Clinical research
• Regulatory affairs
• Risk management
• Medical product safety assessment
• Data analysis
• Epidemiology
• Labeling
• Quality assurance/Quality control
• Compliance
• Medical information

This program has been developed by the Clinical Safety and Pharmacovigilance SIAC.
**DAY 1 | SUNDAY, JANUARY 10**

**7:30-8:30 AM** MORNING TUTORIAL REGISTRATION

**8:30 AM-12:00 PM** MORNING TUTORIALS #1, #2, AND #3

**TUTORIAL #1**

**Signal Detection, Case Assessment and Data Mining in Pharmacovigilance: Current State of the Art**

**Manfred Hauben, MD, MPH**
Senior Director, Risk Management Strategy, Pfizer Inc

This tutorial will provide a theoretical and methodological review of the application of data mining techniques to safety surveillance, its application in signal detection, and the critical role of clinical case assessment. An overview of strategies and specific situation applications will be presented.

**LEARNING OBJECTIVES:**
At the conclusion of this tutorial, participants should be able to:
- Recognize the basic concepts of data mining and principles of signal detection
- Identify specific applications of data mining technology
- Explain the role of clinical case assessment in signal evaluation
- Describe the strengths and limitations of data mining in performance high-quality pharmacovigilance

**TARGET AUDIENCE:**
This tutorial is designed for clinical safety professionals involved in the areas of pharmacovigilance, pharmacoepidemiology, regulatory affairs, quality assurance, medical product safety assessment, and labeling.

**TUTORIAL #2**

**Periodic Safety Update Reports (PSUR): A Guide to the Construction and Analysis of PSURs, ASRs, and DSURs**

**Steve Jolley**
Principal, SJ Pharma Consulting

**Stanley Garbus, MD**
President, Garbus Consulting

This tutorial will explain how to create a PSUR based on the ICH E2C guideline and will describe a methodology for signaling analysis of PSUR data. The tutorial will also address Annual Safety Reports for clinical trials, together with an introduction to the forthcoming Development Safety Update Report (DSUR).

**LEARNING OBJECTIVES:**
At the conclusion of this tutorial, participants should be able to:
- Develop a Period Safety Update report
- Describe the timing for preparation and submission of PSURs
- Analyze data in a PSUR in order to identify potential safety signals
- Discuss key aspects of the ASR and DSUR
- Prepare an Annual Safety Report (ASR) and a Development Safety Update Report (DSUR)

**TARGET AUDIENCE:**
This tutorial is designed for drug safety and pharmacovigilance professionals who are involved in the preparation of PSURs, ASRs, and the soon to be required DSURs. In addition, this tutorial will assist senior pharmacovigilance personnel deploy an intuitive approach to the analysis of periodic safety data in order to identify potential safety signals.
TUTORIAL #3

Applied Epidemiology Techniques for Pharmacovigilance Risk Management
Andrew T. McAfee, MD, MSc
Global Head for Epidemiology
i3 Drug Safety

This tutorial will provide an overview of basic epidemiology methods and study designs. Topics will include design and conduct of case-control studies and cohort studies and an introduction to basic measures of frequency and risk.

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 risk assessment

TARGET AUDIENCE:

This is a basic-level course for individuals who would like a general understanding of the role of epidemiology in pharmacovigilance and risk management.

LEARNING OBJECTIVES:

At the conclusion of this tutorial, participants should be able to:
• Review the various strategies for retrieval and subsequent analysis of MedDRA-coded data in clinical safety and pharmacovigilance
• Discuss the issues relating to MedDRA versioning

TARGET AUDIENCE:

This tutorial is designed for pharmacovigilance and clinical research professionals, clinical data managers, medical writers, and regulatory affairs professionals who already have a basic knowledge of MedDRA and wish to explore the implications of its use in clinical safety and pharmacovigilance.

TUTORIAL #5

Pharmacovigilance and Risk Management Planning
G. K. (Dina) Anand, MD
Global Medical Safety
Johnson & Johnson Pharmaceutical Research and Development

John A. Clark, MD, MSPH
RiskBenefits, LLC

This tutorial will examine methods for approaching and writing risk management documents throughout the life-cycle of a healthcare product. The session will place current EMEA and FDA regulatory requirements and standards, and ICH guidelines for pharmacovigilance planning, into an overall context. Examples will be provided that demonstrate general principles of risk assessment and minimization. The strategic challenges that high quality risk management programs pose for a global biopharmaceutical industry will be addressed.

LEARNING OBJECTIVES:

At the conclusion of this tutorial, participants should be able to:
• Describe the four general development steps (safety specification, pharmacovigilance plan, determination of need for risk minimization, risk minimization plan) for assessing and managing safety risk issues
• Discuss how ICH, FDA, and EMEA risk management guidance documents and formats can be used to develop global risk management programs that are also acceptable in local regulatory environments
• Identify problematic features of risk management programs that decrease their usefulness, such as excessive restriction of use in patients who are appropriate for treatment
• Describe key decision points and methods that suggest a need for program change and/or redesign

TARGET AUDIENCE:

This tutorial is designed for professionals involved with premarketing and postmarketing pharmacovigilance, clinical trials, pharmacoepidemiology, regulatory affairs, risk management and labeling.
DAY 2 | MONDAY, JANUARY 11

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

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

8:45-10:00 AM KEYNOTE PRESENTATION
Global Regulatory Outlook: Current Landscape and Emerging Markets
E. Stewart Geary, MD
Vice President
Eisai Co., Ltd., Japan

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-5:00 PM SESSION 1
Regulations for Pharmacovigilance and Medical Product Safety: National and International Perspectives

- EMEA Pre-and Post-marketing Regulatory Update — via teleconference (1 hour)
  Sabine Brosch, PhD, PharmD
  Scientific Administrator Pharmacovigilance and Risk Management
  European Medicines Agency, European Union

- MHRA Pre-and Post-marketing Regulatory Update (45 minutes)
  Mick Foy
  Group Manager, Div. of Vigilance Risk Management of Medicines, MHRA

12:15-1:15 PM LUNCHEON

2:45-3:15 PM REFRESHMENT BREAK

3:00-4:30 PM SESSION 4
Pre-marketing Assessment of Drug Safety

DAY 3 | TUESDAY, JANUARY 12

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

8:30 AM-11:30 AM SESSION 2
Early Understanding of Safety and Risk

The Principles of Program Design (30 minutes)
Joanna F. Haas, MD, MSc
Vice President, Pharmacovigilance/Medical Information
Genzyme Corporation

Preparing for Pre-Marketing Clinical Trials - Determining What Studies are Needed and How to Evaluate and Review the Study Protocols for Safety and Risk (1 hour)
Brian J. Ledwith, PhD
Executive Director, Safety Assessment
Merck & Company, Inc.

10:00-10:30 AM REFRESHMENT BREAK

11:30 AM-12:00 PM ASK THE EXPERTS – QUESTION AND ANSWER PANEL

12:00-1:00 PM LUNCHEON

1:00-2:30 PM SESSION 3
Safety Reporting for Drugs and Biologics

Basic Requirements for Safety Reporting (30 minutes)
Thomas Steinbach, MD, PhD, FFPM (Dis)
Germany

Establishing Safety Profiles, Individual Case Safety Reports (ICSR), Aggregate Reports (Annual Safety Reports (ASRs), DSURs, IND Annual Reports) (30 minutes)
Ellis Unger, MD
Deputy Director, Division of Cardiovascular and Renal Products
CDER, FDA

Integrated Summary of Safety (ISS) (30 minutes)
Sally Van Doren, PharmD
President & CEO
BioSoteria, Inc.

2:30-3:00 PM REFRESHMENT BREAK

3:00-4:30 PM SESSION 4
Pre-marketing Assessment of Drug Safety

Data Safety Monitoring Committees - Update and Current Issues (30 minutes)
Barton Cobert, MD
President,
BLCMD Associates LLC
Pre-marketing Statistical Information and Analysis, NDA Safety (1 hour)
Chuck Cooper, MD
Senior Safety Policy Advisor, Safety Policy and Communication Staff
CDER, FDA

4:30-5:00 PM  ASK THE EXPERTS – QUESTION AND ANSWER PANEL

5:00-6:00 PM  NETWORKING RECEPTION

DAY 4 | WEDNESDAY, JANUARY 13

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

8:30-10:00 PM  SESSION 5
How to Prepare Risk Management Documentation

Risk Management Plans in the EU (30 minutes)
Thomas Steinbach, MD, PhD, FFPM (Dis)
Germany

Risk Evaluation and Mitigation Strategies in the US (30 minutes)
Kelly D. Davis, MD
Vice President, Epidemiology & Risk Management
United BioSource Corporation

Risk Management Plans in the Asia/Pacific Rim Area (30 minutes)
E. Stewart Geary, MD
Vice President
Eisai Co., Ltd.
Japan

10:00-10:30 AM  REFRESHMENT BREAK

10:30 AM-11:40 AM  SESSION 6
Spontaneous Reporting and Beyond

Basic Requirements for Safety Reporting (30 minutes)
Toni Piazza-Hepp, PharmD
Associate Director for Regulatory Affairs
Office of Surveillance and Epidemiology
CDER, FDA

Signaling / Expedited Aggregate Reporting (CIOMS 8) (30 minutes)
William W. Gregory
Senior Director, Safety and Risk Management
Pfizer Inc.

Post-authorization Safety Studies, Registries, Clinical and Epidemiology Studies (30 minutes)
Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries & Risk Management
United BioSource Corporation

11:40 AM-12:00 PM  ASK THE EXPERTS – QUESTION AND ANSWER PANEL

12:00-1:00 PM  LUNCHEON

1:00-2:30 PM  SESSION 7
Clinical Safety and Pharmacovigilance Inspections: FDA, European Union, and Japanese Approaches

FDA Approach (30 minutes)
Carol Krueger, RN, BSN
Consumer Safety Officer
Surveillance Programs Team
CDER, FDA

European Approach - via teleconference (30 minutes)
Fergus Sweeney, PhD
Head, Compliance and Inspections
European Medicines Agency, European Union
Ana Rodriguez, PhD
Head of Section Clinical and Non-Clinical Compliance
European Medicines Agency, European Union

Japanese Approach (30 minutes)
Mr. Shinya Yamauchi
Operating Officer, Pharmacovigilance Department
Otsuka Pharmaceutical Co., Ltd.

2:30-3:00 PM  REFRESHMENT BREAK

3:00-4:30 PM  SESSION 8
Risk Communications

FDA Transparency and the FDA Risk Communication Advisory Committee (30 minutes)
Lee Zwanziger, PhD
Senior Science Policy Analyst
Designated Federal Officer for the Risk Communication Advisory Committee
FDA

Patient-focused Labeling and Communication (30 minutes)
Mary Willy, PhD
Deputy Director, Division of Risk Management
Office of Surveillance and Epidemiology
CDER, FDA

Healthcare Provider-focused Communications (30 minutes)
Helen Hochstetler, PharmD
Medical Information Consultant
Lilly USA, LLC

Nayan Acharya, MBBS, MRCP, MFPM
Senior Director, Office of Risk Management & Pharmacoepidemiology
Eli Lilly and Company

New Technologies
Jonathan Richman
Director of Strategic Planning
Bridge Worldwide

4:30-5:00 PM  ASK THE EXPERTS – QUESTION AND ANSWER PANEL

5:00 PM  CONFERENCE ADJOURNS
REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

9th Annual DIA Conference on Contemporary Pharmacovigilance and Risk Management Strategies
Event #10002 • Tutorials: January 10 • Workshop: January 11-13, 2010 Renaissance Washington DC Hotel, Washington, DC, USA

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

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TUTORIALS
#1 Signal Detection, Case Assessment and Data Mining in Pharmacovigilance: Current State of the Art
#2 Periodic Safety Update Reports (PSUR): A Guide to the Construction and Analysis of PSURs, ASRs, and DSURs
#3 Applied Epidemiology Techniques for Pharmacovigilance
#4 Risk Management
#5 Pharmacovigilance and Risk Management Planning

TO RECEIVE A TABLETOP EXHIBIT APPLICATION, PLEASE CHECK

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

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CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc., P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. if included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Renaissance Washington DC Hotel is holding a block of rooms at the reduced rate below until December 18, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $234 Double $234

Please contact the Renaissance Washington DC Hotel by telephone at +1-800-HOTELS-1 or +1-202-898-9000 and mention the DIA event. The hotel is located at 999 9th St. NW, Washington, DC 20001, USA.

CANCELLATION POLICY: On or before January 4, 2010 Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

TABLETOP EXHIBIT INFORMATION
Attendees may visit the tabletop exhibits during the event and receptions.
Contact Jeff Korn, Exhibits Associate, Phone +1.215.442.6184
Fax +1.215.442.6199, email Jeff.Korn@diahome.org

EVENT INFORMATION
Contact Ellen Diegel, Program Manager, Phone +1.215.442.6158
Fax +1.215.442.6199, email Ellen.Diegel@diahome.org

Please check the applicable category:
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