For those new to pharmaceutical safety

Adverse Drug Events in Premarketing Clinical Trials and Postmarketing Pharmacovigilance
The Compliance, Medical Assessment and Risk Management Continuum

October 16-17, 2007 | Loews Hotel, Philadelphia, PA, USA

OVERVIEW
Clinical trial safety and postmarketing pharmacovigilance constitute a risk management continuum, in which a pharmaceutical's benefit/risk balance is monitored and re-evaluated on an ongoing basis. A major aspect of this critical public health function is performance of high-quality medical assessment of adverse drug events in both pre- and postmarketing realms.

For those new to pharmaceutical safety, it is imperative to become familiar with regulatory requirements and initiatives, both US and international, which form the basis for compliance standards. In this conference, a range of topics relating to premarketing clinical trials and postmarketing pharmacovigilance will be addressed, providing attendees with an overview of the various activities performed by safety specialists.

LEARNING OBJECTIVES
At the conclusion of this conference, participants should be able to:

- Outline pre- and postmarketing safety reporting requirements in US and Europe
- Discuss the clinical pharmacological basis of adverse events
- Explain how to perform quality medical assessment of individual case safety reports (ICSRs)
- List the key offices in FDA and EMEA involved in premarketing clinical drug safety, postmarketing pharmacovigilance and pharmacoepidemiology
- Provide an overview of risk management initiatives in premarketing drug approval and postmarketing
- Review the structure and products of ICH and CIOMS working groups
- Describe the European Clinical Trial Directive and EudraVigilance
- Compare and contrast principles of randomized clinical trials and observational studies
- Discuss the use of MedDRA® and data mining algorithms in pharmacovigilance
- Identify biostatistical considerations in clinical trials and pharmacovigilance
- Explain the decision-making and implementation processes in product labeling
- Describe how to prepare for safety-related regulatory body inspections
- List requirements for Data Safety Monitoring Boards and Institutional Review Boards that impact clinical trial safety

WHO SHOULD ATTEND
Professionals interested in gaining at least basic knowledge of contemporary drug 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

PROGRAM COMMITTEE
STEPHEN A. GOLDMAN, MD, FAPM, DFAPA
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VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!
DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

Member Early-bird Rate — Register for this conference by September 25 and Save $175!

Back-to-back with Harmonization of Risk Management Plans
October 18-19, 2007
Loews Hotel, Philadelphia, PA
See pages 4 & 6 for details about this conference and discount opportunities.
MONDAY • OCTOBER 15

NO PREREGISTRATION WILL BE AVAILABLE FOR THIS PROGRAM

TUESDAY • OCTOBER 16

7:00-8:30 AM   REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:40 AM   WELCOME AND OPENING REMARKS
Stephen A. Goldman, MD, FAPM, DFAPA
Managing Member
Stephen A. Goldman Consulting Services, LLC
Adjunct Assistant Professor of Psychiatry
Uniformed Services University of the Health Sciences

8:40-11:45 AM  MORNING SESSION
US AND EU REGULATIONS FOR CLINICAL TRIAL SAFETY AND POSTMARKETING PHARMACOVIGILANCE

8:40-8:45 AM   OPENING REMARKS
MORNING SESSION HOST
A. Michael Bloh, RPh, MBA
Principal, Drug Safety Net LLC

8:45-9:15 AM   HISTORY, STRUCTURE AND FUNCTION OF FDA
A. Michael Bloh, RPh, MBA

9:15-9:40 AM   OVERVIEW, STRUCTURE AND FUNCTION OF EMEA
Sabine Brosch, PhD, MSc
Deputy Head of Sector, Pharmacovigilance and Postauthorization Safety and Efficacy, European Medicines Agency (EMEA), EU

9:40-10:05 AM  OVERVIEW, STRUCTURE AND FUNCTION OF PMDA
Kaori Nomura
Chief, Safety Information Division, Office of Safety Pharmaceuticals and Medical Devices Agency, (PMDA), Japan

10:05-10:20 AM  REFRESHMENT BREAK

10:20-10:50 AM  OVERVIEW, STRUCTURE AND FUNCTION OF ICH AND CIOMS
William Gregory, PhD
Director, Safety and Risk Management
Pfizer Inc

10:50-11:30 AM  US PRE- AND POSTMARKETING SAFETY REGULATIONS
Stephen A. Goldman, MD, FAPM, DFAPA

11:30-11:55 AM   QUESTION & ANSWER PERIOD

11:55 AM-1:00 PM   LUNCHEON

1:00-5:00 PM   AFTERNOON SESSION

CLINICAL TRIALS, OBSERVATIONAL STUDIES AND MedDRA®

1:00-1:05 PM   OPENING REMARKS
AFTERNOON SESSION HOST
David Goldsmith MD, FISPE
President, Senior Consultant
Goldsmith Pharmacovigilance Systems

1:05-1:50 PM   EU PRE- AND POSTMARKETING SAFETY REGULATIONS
María Grazia Zurlo, MD
Vice President, Safety and Risk Management
EU Qualified Person for Pharmacovigilance
Pfizer Inc, Italy

1:50-2:35 PM   EUROPEAN CLINICAL TRIAL DIRECTIVE AND EUDRAVIGILANCE
Mariette Boerstoel-Streefland, MD, MSc
Executive Director, Pharmacovigilance/Risk Management
Forest Research Institute, Forest Laboratories, Inc.

2:35-2:50 PM   REFRESHMENT BREAK

2:50-3:20 PM   DESIGN AND CONDUCT OF RANDOMIZED CLINICAL TRIALS
Alexander M. Walker, MD, DrPH
i3 Drug Safety
Adjunct Prof. of Epidemiology, Harvard School of Public Health

3:20-3:50 PM   DESIGN AND CONDUCT OF OBSERVATIONAL STUDIES
David E. Lilienfeld, MD, MPH, MSEngin, MBA, FACE, FISPE, FAHA
Senior Director, Clinical Development
FibroGen, Inc.

3:50-4:20 PM   INTRODUCTION TO MedDRA®: TERMINOLOGY AND CODING
David Goldsmith, MD, FISPE

4:20-5:00 PM   PANEL DISCUSSION: INTEGRATING SAFETY REPORTING REQUIREMENTS WITHIN PRE- AND POSTMARKETING CLINICAL STUDIES
MODERATOR
David Goldsmith, MD, FISPE

PANELISTS
Maria Grazia Zurlo, MD
Mariette Boerstoel-Streefland, MD, MSc
David E. Lilienfeld, MD, MPH, MSEngin, MBA, FACE, FISPE, FAHA
Alexander M. Walker, MD, DrPH

5:30-6:30 PM   NETWORKING RECEPTION
SPONSORED BY THE CLINICAL SAFETY AND PHARMACOVIGILANCE SPECIAL INTEREST AREA COMMUNITY
Wednesday • October 17

7:30-8:30 AM  Registration and Continental Breakfast

8:30 AM-12:00 PM  Morning Session

Pre- and Postmarketing Adverse Events, Statistical Considerations and Special Clinical Trial Topics

8:30-8:35 AM  Opening Remarks
Morning Session Host
Anshu Vashishtha, MD, PhD, MACP, RAC
Vice President
Pharmacovigilance and Medical Affairs
Sciformix

8:35-9:20 AM  The Clinical Pharmacological Basis of Adverse Events
Stephen A. Goldman, MD, FAPM, DFAPA

9:20-10:05 AM  Assessment of Individual Case Reports (ICSRs)
Anshu Vashishtha, MD, PhD, MACP, RAC

10:05-10:35 AM  A Primer on Biostatistics
Warren B. Bilker, PhD
Associate Professor of Biostatistics at the Hospital of the University of Pennsylvania
University of Pennsylvania School of Medicine

10:35-10:55 AM  Refreshment Break

10:55-11:30 AM  Special Topics in Clinical Trials (Data Safety Monitoring Boards; Institutional Review Boards)
David Goldsmith MD, FISPE

11:30 AM-12:00 PM  Question & Answer Period

12:00-1:00 PM  Luncheon

1:00-4:40 PM  Afternoon Session

Management and Minimization of Medical Product Risk

1:00-1:05 PM  Opening Remarks
Afternoon Session Host
Stephen A. Goldman, MD, FAPM, DFAPA

1:05-1:10 PM  Labeling, Packaging, and Medication Error Assessment
A. Michael Bloh, RPh, MBA

1:10-1:45 PM  FDA Safety Inspections
Carol L. Krueger, RN
Consumer Safety Officer
Division of Compliance, Risk Management, and Surveillance
CDER, FDA

2:15-2:55 PM  Pharmacovigilance Planning: The E2E Guideline
Wanju Dai, MD, DrPH
Vice President and Global Head
Epidemiology
sanofi-aventis

2:55-3:10 PM  Refreshment Break

3:10-3:55 PM  Risk Management in Pre- and Postmarketing
Maria Grazia Zurlo, MD

3:55-4:40 PM  Panel Discussion: The Pre- and Postmarketing Risk Management Continuum – A Brave New World
Moderator
Stephen A. Goldman, MD, FAPM, DFAPA

Panelists
Carol L. Krueger, RN
A. Michael Bloh, RPh, MBA
Warren B. Bilker, PhD
Wanju Dai, MD, DrPH
Maria Grazia Zurlo, MD

4:40 PM  Conference Adjourned

See page 5 for continuing education and travel/hotel information.
Back-to-back Conference
Members who register for both conferences can SAVE AN ADDITIONAL $175!

Harmonization of Risk Management Plans
October 18-19, 2007 | Loews Hotel, Philadelphia, PA, USA

Understanding Risk Management and Pharmacovigilance Issues Across Borders

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

- Discuss the fundamental aspects of RMPs as applied to medicinal products, therapeutic biologics, and vaccines;
- Recognize similarities and differences in RMP requirements in several regulatory jurisdictions, including Canada, the European Economic Area, Japan, and the US; and.
- Discuss the role of RMPs from the perspectives of marketing authorization holders, regulatory authorities, and other stakeholders.

CONFERENCE HIGHLIGHTS
- Learn why risk management plans (RMPs) are important to your company from a global regulatory perspective and the pros and cons of a global vs. local approach to developing RMPs;
- Hear regulators and industry representatives from around the world explain RMPs as they apply to medicinal products, therapeutic biologics, and vaccines, and how a harmonized RMP can promote efficient, evidence-based decision-making to support the best use of marketed products and thereby enhance public health;
- Participate in hands-on exercises to create a harmonized RMP for a fictitious product; and
- Interact with experts from competent authorities and marketing application holders during hands-on sessions, extensive Q&A, and in-depth panel discussions.

WHO SHOULD ATTEND
Professionals with basic to intermediate levels of experience in pharmacovigilance and risk management and who are responsible for:

- Developing and evaluating RMPs
- Generating and assessing drug safety signals
- Organizing post-authorization safety studies

OVERVIEW
This conference will teach you how to identify and organize essential components of an RMP vis-à-vis well-described risks, poorly understood risks, and certain potential risks of products that may be made available to patients and healthcare providers in different regions of the world.

It includes hands-on exercises in addition to didactic presentations, interactive examples, and panel discussions.

PROGRAM CHAIR
WILLIAM W. GREGORY
Director, Safety and Risk Management, Pfizer Inc

PROGRAM COMMITTEE/PRESENTERS
MARC BERTHIAUME, MD
Director, Marketed Pharmaceuticals and Medical Devices Bureau, Health Canada
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KAORI NOMURA
Chief, Safety Information Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 13.25 AMA PRA Category 1 Credit(s)™. Physicians should only claim 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 is designated for 13.25 contact hours or 1.325 continuing education units (CEUs).

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.3 continuing education units (CEUs) to participants who successfully complete this program.

NURSING

The Drug Information Association will offer nursing credits for this program in collaboration with Corexcel. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center’s Commission on Accreditation. This program is designated a maximum of 13 nursing contact hours.

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Recording of information, in any type of media, is prohibited at all DIA events without prior written consent from DIA.

TRAVEL AND HOTEL

The most convenient airport is Philadelphia International Airport and attendees should make airline reservations as early as possible to ensure availability. The Loews Hotel is holding a block of rooms at the reduced rate below until September 24, 2007, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

| Single $209 | Double $209 |

Please contact the Loews Hotel by telephone at +1-215-627-1200 and mention the DIA event. The hotel is located at 1200 Market Street, Philadelphia, PA 19107, USA.

UNITED AIRLINES & US AIRWAYS

Save through Area Pricing and Discount Fees

To obtain schedule information and the best fares, call United Airlines’s Specialized Meeting Reservations Center at 1-800-521-4041. Make sure you refer to Meeting ID Number 571AK. Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

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. Participants who register at the discounted rate for both conferences are not eligible for the group discount.

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.

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.

DRUG INFORMATION ASSOCIATION http://www.diahome.org

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For those new to pharmaceutical safety

ADVERSE DRUG EVENTS IN PREMARKETING CLINICAL TRIALS AND POSTMARKETING PHARMACOVIGILANCE: The Compliance, Medical Assessment, and Risk Management Continuum

OCTOBER 16-17, 2007 | Loews Hotel, Philadelphia, PA, USA
(Event ID #07022)

Register online or fax this page to +1-215-442-6199

CONTACT & TABLETOP EXHIBIT INFORMATION: Attendees may visit the tabletop exhibits during the event and during receptions (if applicable). Event information: Contact Ellen Diegel at the DIA office by telephone +1-215-442-6158, fax +1-215-442-6199 or email Ellen.Diegel@diahom.org. Tabletop exhibit - information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahom.org. For tabletop exhibit space, please check the box below.

☐ To receive a tabletop exhibit application, please check.

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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. See page 5 for complete details.

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

MEMBER EARLY-BIRD OPPORTUNITY (ID # 07022)

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Join DIA now to qualify for the early-bird member fee! www.diahom.org
To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to governments/academia/nonprofit members.

Nonmember Fee

US $1470

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not want membership.

I want to be a DIA member ☐ I do NOT want to be a DIA member ☐

Discount Fees

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*If paying a nonmember fee, please check one box above, indicating whether you want membership.

CANCELLATION POLICY FOR ID# 07022: On or before OCTOBER 10, 2007

Administrative fee that will be withheld from refund amount:

Member or Nonmember = $200

Government or Academia or Nonprofit (Member or Nonmember) = $100

Tutorial (if applicable) = $50

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.

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Members who register for both conferences can SAVE AN ADDITIONAL $175!

SAVE AN ADDITIONAL $175!

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☐ Visa ☐ MC ☐ AMEX

Exp Date

☐ 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 dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

Payment must be in US currency. A bank transfer administrative fee that will be withheld from refund amount:

Member or Nonmember = $200

Government or Academia or Nonprofit (Member or Nonmember) = $100

Tutorial (if applicable) = $50

CANCELLATION POLICY FOR COMBINED EVENTS – On or before OCTOBER 10, 2007

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SAVE AN ADDITIONAL $175!