Monitors and Evaluating the Fetal Effects of Drug Exposure During Pregnancy

May 1–3, 2006 | Washington Marriott Hotel, Washington, DC

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

- Explain basic embryogenesis and fetal development and how drugs can cause birth defects
- Recognize how additional premarketing clinical studies can help delineate fetal risks when developing a pharmaceutical product that is a potential human teratogen
- Identify when a postmarketing pregnancy exposure registry is indicated
- Distinguish when data from a pregnancy exposure registry indicate an event of special interest and when additional analyses or confirmatory studies should be undertaken
- Describe the impact of HIPAA and informed consent on pregnancy exposure registry design and the critical role of a scientific advisory board in conducting such a registry
- Explain international requirements and guidelines for monitoring drug exposures during pregnancy and describe what databases and general registries currently exist

OVERVIEW
Increasing emphasis is being placed on drug safety during pregnancy – from the conduct of pregnancy exposure registries to evaluate the teratogenic potential of pharmaceutical products to formal pregnancy prevention risk management programs to minimize exposures to known human teratogens.

The purpose of this meeting is to review and discuss various aspects of drug development and surveillance related to delineating fetal risks associated with drug exposures during pregnancy.
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 13.75 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 up to 13.75 contact hours or 1.375 continuing education units (CEUs). 286-000-06-002-L04.

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 1.4 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 13.2 nursing contact hours.

If you would like to receive a statement of credit, you must attend the program and return the credit request and evaluation forms to the DIA. Statements of credit will be issued within 30 days of receipt of these forms.

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.

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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 any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

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**MONDAY • MAY 1**

12:00-1:00 PM  **REGISTRATION**

1:00-1:30 PM  **WELCOME AND OPENING REMARKS**

Annette Stemhagen, DrPH, FISPE
Vice President, Epidemiology and Risk Management, United Biosource Corporation

Sandra Kweder, MD
Deputy Director, Office of New Drugs, FDA

**SESSION I**

**REPRODUCTIVE TOXICOLOGY AND PRE-MARKETING CONSIDERATIONS**

SESSION CHAIRPERSON

Sandra Kweder, MD
Deputy Director, Office of New Drugs, FDA

1:30-2:30 PM  **TERATOLOGY 101**

Jan Friedman, MD, PhD
Professor, Department of Medical Genetics, University of British Columbia

2:30-3:30 PM  **REPRODUCTIVE TOXICOLOGY – WHAT DOES IT MEAN FOR HUMANS?**

Wafa Harrouk, PhD
Pharmacology/Toxicology Reviewer, Division of Reproductive and Urologic Products, FDA

3:30-3:45 PM  **REFRESHERMENT BREAK**

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**3:45-4:45 PM  DESIGN CONSIDERATIONS FOR CLINICAL STUDIES**

Jill Lindstrom, MD, FAAD
Lead Medical Officer, FDA

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**4:45-5:30 PM  WHEN IS A POST-MARKETING REGISTRY NEEDED?**

Janet D. Cragan, MD, MPH
Medical Officer, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention

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**5:30-6:30 PM  RECEPTION**

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**TUESDAY • MAY 2**

8:00-9:00 AM  **REGISTRATION AND CONTINENTAL BREAKFAST**

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**SESSION II**

**METHODOLOGICAL CONSIDERATIONS FOR POST-MARKETING STUDIES**

SESSION CHAIRPERSON

Chi-Sing Nip, PharmD
Associate Director, Drug Safety Risk Management, Hoffmann-La Roche Inc.

9:00-10:00 AM  **DESIGN CONSIDERATIONS FOR POST-MARKETING STUDIES**

Christina Chambers, PHD, MPH
Assistant Professor, Department of Pediatrics and Family and Preventive Medicine, University of California San Diego School of Medicine
SESSION III

EVALUATING DATA ON THE EFFECTS OF DRUG EXPOSURE IN PREGNANCY

SESSION CHAIRPERSON
Dianne L. Kennedy, RPh, MPH
Program Manager, Pregnancy and Lactation Team, FDA

1:30-3:00 PM
CRITICAL FACTORS IN EVALUATING DATA ON THE EFFECTS OF DRUG EXPOSURE IN PREGNANCY
Anthony R. Scialli, MD
Senior Scientist, Sciences International Inc.

3:00-3:30 PM
REFRESHMENT BREAK

3:30-4:30 PM
CASE STUDIES
Anthony R. Scialli, MD
Senior Scientist, Sciences International Inc.

4:30-5:30 PM
IDENTIFYING A SIGNAL: CONSIDERATIONS FOR DATA ANALYSIS AND PRESENTATION
Jan Friedman, MD, PhD
Professor, Department of Medical Genetics, University of British Columbia

SESSION IV

PERSPECTIVES FOR THE FUTURE

SESSION CHAIRPERSON
Janet D. Cragan, MD, MPH
Medical Officer, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention

9:00-9:45 AM
HUMAN REPRODUCTION RISK ASSESSMENT OF DRUGS: THE EUROPEAN PERSPECTIVE
Jan Willem Van der Laan, PhD
Head Pharmacology Toxicology Assessment, RIVM

9:45-10:30 AM
DRUGS AND PREGNANCY: MEETING CLINICAL NEEDS
Sandra Kweder, MD
Deputy Director, Office of New Drugs, FDA

10:30-10:45 AM
REFRESHMENT BREAK

10:45-11:30 AM
COMPREHENSIVE SYSTEMATIC POST-MARKETING SURVEILLANCE FOR ASTHMA MEDICATIONS IN PREGNANCY – A MODEL APPROACH
Christina Chambers, PHD, MPH
Assistant Professor, Department of Pediatrics and Family and Preventive Medicine, University of California San Diego School of Medicine

11:30-12:15 AM
INSIGHT INTO THE FUTURE OF MONITORING DRUG USE IN PREGNANCY
Hugh Tilson, MD, DRPH
Clinical Professor of Public Health Leadership, University of North Carolina

12:15 PM
WORKSHOP ADJOURNED
Monitoring and Evaluating the Fetal Effects of Drug Exposure During Pregnancy

Meeting ID #06011
Washington Marriott Hotel
Washington, DC, USA
May 1-3, 2006

Sessions will include:

- Reproductive Toxicology and Pre-marketing Considerations
- Methodological Considerations for Post-marketing Studies
- Evaluating Data on the Effects of Drug Exposure in Pregnancy
- Perspectives for the Future

Register by APRIL 10, 2006
SAVE $175

May 1-3, 2006
Washington, DC, USA
Meeting ID #06011

the Fetal Effects of Drug Monitoring and Evaluating

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Charitable Nonprofit/Academia (Full-time)

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CANCELLATION POLICY: On or before APRIL 25, 2006

Administrative fee that will be withheld from refund amount:

Member or Nonmember = $200

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

Tutorial = $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.

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.

CANCELLATION POLICY: On or before APRIL 10, 2006

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

CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the meeting and during receptions (if applicable).

Meeting information: Contact Joanne Wallace at the DIA office by telephone +1-215-442-6199, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org.

Tabletop exhibit information: Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box below.

To receive a tabletop exhibit application, please check.

GROUP DISCOUNTS (not available online or on already discounted fees)

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 3 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, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY

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On or before APRIL 10, 2006 After APRIL 10, 2006

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Nonmember Fee US $1430 ❑

Last Name Check if part of group registration ❑ First Name M.I.

Degrees Dr. ❑ Mr. ❑ Ms. ❑

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

Phone Number Fax Number Required for confirmation

email Required for confirmation

Group Registrant #1 Last Name First Name Completed form required for each group registrant

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

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Signature ________________________________

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. You may pay in the currency of your choice. Your name and company, as well as the Meeting ID # must be included on the transfer document to ensure payment to your account.

REGISTRATION FORM Do not remove mailing label. Please return this entire page.

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