DIA

EARLY-BIRD DISCOUNT

MEMBERS SAVE $75

RENAISSANCE WASHINGTON HOTEL • 999 NINTH STREET NW • WASHINGTON, DC, USA

WASHINGTON, DC MAY 24-25, 2004

Pregnancy Exposure Registries

Evaluating the Teratogenic Potential of Pharmaceutical Products Used at Clinical Doses

TARGET AUDIENCE

Professionals who work in the areas of:

- Healthcare
- Pharmacoepidemiology
- Clinical safety and pharmacovigilance
- Drug safety
- Clinical research and development
- Medical communications and information
- Quality of life
- Health economics
- Outcomes research

OVERVIEW

Pregnancy exposure registries are currently being used to evaluate the teratogenic potential of pharmaceutical products. The purpose of this meeting is to review and discuss the design and implementation of pregnancy registries and the evaluation and utilization of data gathered. This workshop is organized into three half-day sessions.

The first half-day session will focus on the importance of studying drug exposure during pregnancy and the FDA Guidance that provides recommendations to consider when undertaking the design of a registry. Procedural areas that need special attention (IRB, HIPAA, Advisory Committee, etc.) will also be discussed.

The second half-day session will focus on a review of currently operating pregnancy registry models. Specifically, this session will compare and contrast a variety of registry designs, their application, and their ability to collect comprehensive safety information and detect a safety signal.

The third half-day session will focus on evaluating data on the effects of drug exposure during pregnancy and how the data can be used to enhance product labeling and risk management efforts.

PROGRAM COMMITTEE

Susan Ackermann Shiff, PhD
Global Head, Risk Management
Hoffmann-La Roche Inc.

Janet D. Cragan, MD, MPH
Medical Director, Metropolitan Atlanta Congenital Defects Program, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention

Dianne L. Kennedy, RPh, MPH
Program Manager, Pregnancy Labeling
FDA

THIS PROGRAM WAS DEVELOPED BY THE CLINICAL SAFETY AND PHARMACOVIGILANCE SPECIAL INTEREST AREA COMMUNITY SIAC

ONLINE REGISTRATION IS AVAILABLE! www.diahome.org

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

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 11.25 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmaceutical education. This program is designated for 11.25 contact hours or 1.125 continuing education units (CEU's). Pharmacists will be required to complete a program evaluation form. Statements of credit will be mailed to participants within one month of program completion. 286-000-04-019-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 1.1 continuing education units (CEUs) to participants who successfully complete this program. To receive a credit certificate, participants must attend the program, and complete the CE Request and Evaluation Forms and return them to DIA.

If you would like to receive a statement of credit, you must attend the program (and tutorial, if applicable), 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.

Learning Objectives: At the conclusion of this meeting, participants should be able to:

- Identify when a pregnancy exposure registry is necessary and how surveillance data can be used to inform health care professionals and the public of the teratogenic potential of a pharmaceutical product being studied
- Evaluate the utility of different registry design options and the strengths and weaknesses of each
- Recognize the critical factors to consider when evaluating data on the effects of drug exposure in pregnancy

SUNDAY • MAY 23

6:00-8:00 PM REGISTRATION

MONDAY • MAY 24

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

8:00-8:05 AM WELCOME AND OPENING REMARKS
Annette Stemhagen, DrPH, FISPE
Vice President, Strategic Development Services
COVANCE PERIAPPROVAL SERVICES, INC.

8:05 AM-12:15 PM SESSION I

PREGNANCY EXPOSURE REGISTRIES: GOALS, OBJECTIVES AND DESIGN ISSUES

CHAIRPERSON
Susan Ackermann Shiff, PhD
Global Head, Risk Management
HOFFMANN-LA ROCHE INC.

This session will provide information about the settings in which exposure registries may be effective. The speakers will outline the importance of monitoring pregnancy exposures after a drug is marketed, identify the purpose and goals of the registry approach, delineate the circumstances under which establishing a pregnancy exposure registry may be indicated, and emphasize some of the important considerations in registry design and conduct. Specifically, the FDA Guidance for Industry on Establishing Pregnancy Exposure Registries will be reviewed; issues of privacy and informed consent relevant to pregnancy registries will be discussed; key issues in registry design will be identified, including the appropriate use of a comparison group, determining the length of time over which data should be collected, effectively utilizing an advisory committee, and detecting a signal of increased risk. The session will set the stage for subsequent more detailed discussions of registry design and implementation.

IMPORTANCE OF STUDYING DRUG EXPOSURE

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

INDUSTRY PERSPECTIVE
Alan Goldhammer, PhD
Associate Vice President, Regulatory Affairs
PHRMA

OVERVIEW OF FDA'S GUIDANCE FOR INDUSTRY: ESTABLISHING PREGNANCY EXPOSURE REGISTRIES
Dianne L. Kennedy, RPh, MPH
Program Manager, Pregnancy Labeling Team
CDER, FDA

IMPORTANT CONSIDERATIONS IN REGISTRY DESIGN
Elizabeth B. Andrews, MPH, PhD
Vice President, Pharmacoepidemiology and Risk Management
RTI HEALTH SOLUTIONS

CONSIDERATIONS FOR DATA ANALYSIS AND PRESENTATION
Jan M. Friedman, MD, PhD
Medical Geneticist, Departments of Medical Genetics
UNIVERSITY OF BRITISH COLUMBIA, CANADA

10:30-10:45 AM **REFRESHMENT BREAK**

Utilizing an Independent Advisory Committee
Janet D. Cragan, MD, MPH
Medical Director, Metropolitan Atlanta Congenital Defects Program, National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention

Legal Implications: The Impact of IRB Approval, Ensuring Patient Confidentiality and the Implications of HIPAA
Peter Beckerman, JD
Associate Chief Counsel for Drug and Biologics
HHS Office of General Counsel, food and Drug Division

12:15-1:15 PM **LUNCHEON**

1:15-5:00 PM SESSION II

Registry Models and Design Options

CHAIRPERSON

Dianne L. Kennedy, RPh, MPH
Program Manager, Pregnancy Labeling Team
CDER, FDA

This session will continue the themes from the first session to familiarize participants with the practical issues involved in conducting pregnancy registries. Representatives from different registries that utilize different approaches will share their experience in monitoring exposed pregnancies. Potential topics to be addressed by each speaker include the source and quality of exposure and outcome information; choice of a comparison group; utilization of a scientific advisory committee; criteria for identifying an adverse signal; what may be concluded from the registry data about the risk of a drug exposure; when the registry will stop collecting new data; and what they would do differently next time. By the end of the session, participants should be able to identify the key management and methodologic issues for existing registries, and to appropriately consider these issues when planning new activities to monitor pregnancy exposures.

Single Product/Single Company Models

The Merck Experience
Kristine Shields, MSN, MPH
Associate Director, Clinical Risk Management & Safety Surveillance
Merck Research Laboratories

The GlaxoSmithKline Experience
Alice White, PhD
Vice President, Worldwide Epidemiology
GlaxoSmithKline

Multiproduct/Multicompany Models

The Antiretroviral Experience
Deborah Covington, DrPH
Director, Registries & Epidemiology
Inveresk.

The AED Experience
Diego F. Wyszynski, MD, PhD
Assistant Professor of Medicine and of Epidemiology
Boston University School of Medicine

3:00-3:20 PM **REFRESHMENT BREAK**

Organizations of Teratogen Information Services (OTIS) Model
Christina Chambers, PhD, MPH
Assistant Professor, Department of Pediatrics and Family and Preventative Medicine
UCSD Medical Center

Linked-data System Model: The Vanderbuilt Experience
William Cooper, MD, MPH
Associate Professor of Pediatrics
Vanderbilt School of Medicine

Panel Discussion
Christina Chambers, PhD, MPH
Associate Professor, Department of Pediatrics
UCSD Medical Center
William Cooper, MD, MPH
Assistant Professor of Pediatrics
Vanderbilt School of Medicine
Deborah Covington, DrPH
Director, Registries & Epidemiology
Inveresk
Dianne L. Kennedy, RPh, MPH
Program Manager, Pregnancy Labeling Team
CDER, FDA
Kristine Shields, MSN, MPH
Associate Director, Clinical Risk Management & Safety Surveillance
Merck Research Laboratories
Alice White, PhD
Vice President, Worldwide Epidemiology
GlaxoSmithKline
Diego F. Wyszynski, MD, PhD
Assistant Professor of Medicine and of Epidemiology
Boston University School of Medicine

5:00-6:00 PM **NETWORKING RECEPTION**

Sponsored by the **Clinical Safety and Pharmacovigilance Special Interest Area Community**

TUESDAY • MAY 25

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

9:00 AM-12:30 PM SESSION III

EVALUATING DATA ON THE EFFECTS OF DRUG EXPOSURE IN PREGNANCY

CHAIRPERSON

Janet D. Cragan, MD, MPH
Medical Director, Metropolitan Atlanta Congenital Defects Program, National Center on Birth Defects and Developmental Disabilities
CENTERS FOR DISEASE CONTROL AND PREVENTION

This session will focus on interpreting and using data generated by pregnancy exposure registries. Topics will include a review of the principles of teratology; the use of animal studies to look for evidence of potential human risk; key factors in evaluating individual reports of pregnancy outcomes; and inclusion of registry data in the product label. Issues related to the quality of exposure and outcome information, choice of a comparison group, how to detect a signal of increased risk, and the goals of the registry approach will be revisited through actual case studies using registry data. The session will provide participants with an appreciation of how surveillance data should be used to help health care providers and women better understand the risks of medication use during pregnancy.

CRITICAL FACTORS IN EVALUATING DATA ON THE EFFECTS OF DRUG EXPOSURE IN PREGNANCY AND DATA USE IN SIGNAL DETECTION
Anthony R. Scialli, MD
Department of Obstetrics and Gynecology
GEORGETOWN UNIVERSITY MEDICAL SCHOOL

IMPORTANCE OF ANIMAL DATA FOR COMPARISON WITH HUMAN OUTCOMES
Carole A. Kimmel, PhD
Senior Scientist, National Center for Environmental Assessment, Office of Research and Development
US ENVIRONMENTAL PROTECTION AGENCY

11:00-11:15 AM REFRESHMENT BREAK

CASE STUDIES
Anthony R. Scialli, MD
Department of Obstetrics and Gynecology
GEORGETOWN UNIVERSITY MEDICAL SCHOOL

BRINGING IT ALL TOGETHER: UTILIZATION OF THE DATA FOR LABEL CHANGES AND THE PUBLIC HEALTH
Hugh Tilson, MD, DrPH
Senior Advisor to the Dean, School of Public Health
UNIVERSITY OF NORTH CAROLINA

12:30-1:00 PM SESSION IV

PANEL DISCUSSION

CHAIRPERSON

Hugh Tilson, MD, DrPH
Senior Advisor to the Dean, School of Public Health
UNIVERSITY OF NORTH CAROLINA

PANELISTS

Janet D. Cragan, MD, MPH
Medical Director, Metropolitan Atlanta Congenital Defects Program, National Center on Birth Defects and Developmental Disabilities
CENTERS FOR DISEASE CONTROL AND PREVENTION

Alan Goldhammer, PhD
Associate Vice President, Regulatory Affairs
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Anthony R. Scialli, MD
Department of Obstetrics and Gynecology
GEORGETOWN UNIVERSITY MEDICAL SCHOOL

Susan Ackermann Shiff, PhD
Global Head, Risk Management
HOFFMANN-LA ROCHE INC.

Kathleen Uhl, MD
Team Leader, Pregnancy Labeling
CDER, FDA

1:00-1:05 PM CLOSING REMARKS
Susan Ackermann Shiff, PhD
Global Head, Risk Management
HOFFMANN-LA ROCHE INC.

1:05 PM WORKSHOP ADJOURNED

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. Audio/visual taping of any DIA workshop is prohibited without prior written consent from DIA.

Horsham, PA, USA
Tel: +1-215-442-6100 • Fax: +1-215-442-6199
email: dia@diahome.org

Basel, Switzerland
Tel: +41-61-225-51-51 • Fax: +41-61-225-51-52
email: diaeurope@diaeurope.org

Tokyo, Japan
Tel: +81-3-5322-1336 • Fax: +81-3-5322-2872
email: diajapan@gol.com

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 Hotel is holding a block of rooms at the reduced rate below until April 30, 2004, for the DIA meeting attendees.

Single $209 **Double $209**

To reserve your room, please contact the Renaissance Washington Hotel by telephone at +1-800-HOTELS-1 or +1-202-898-9000 and mention the DIA meeting. The Renaissance Washington Hotel is located at 999 Ninth Street NW, Washington, DC 20001, USA.

CONTACT & TABLETOP EXHIBIT INFORMATION: Attendees are welcome to visit the limited tabletop exhibits during the meeting and receptions. For meeting and tabletop exhibit information, contact Joanne Wallace, Meeting Manager at the DIA office in Horsham, PA by telephone +1-215-442-6180, fax +1-215-442-6199 or email joanne.wallace@diahome.org. **Should you be interested in obtaining space for a tabletop exhibit, please check the box in the REGISTRATION FEE area below.**

UNITED AIRLINES & US AIRWAYS ***Save through Area Pricing!***

DIA has secured a special discount agreement with United Airlines unavailable to the general public. Several pricing options are available, based on dates of travel. You may choose a 5% discount off the lowest applicable fare by calling United's toll-free number **1-800-521-4041** and refer to the **Meeting ID Number 571AK** OR a 10% discount is available off unrestricted coach fares when purchased 7 days in advance. An additional 5% discount will apply when you purchase your tickets at least 30 days in advance of your travel date. Or you may chose Area Pricing, set air fare prices based upon geographical locations. Discounts apply on United, United Express, United code share flights (UA*) operated by US Airways , US Airways Express, and Air Canada scheduled service. Reservationists are on duty 7 days a week, 8:00 am-10:00 pm EST. Mileage Plus members receive full credit for all miles flown to this meeting.

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

CANCELLATION POLICY: **On or before May 18, 2004**

Administrative fee that will be withheld from refund amount: Member/Nonmember = $200 • Government/Academia/Nonprofit (Member/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.

PLEASE CONSIDER THIS FORM AN INVOICE

Pregnancy Exposure Registries

Meeting I.D. # 04024 – May 24-25, 2004

Renaissance Washington Hotel, Washington, DC, USA

Registration Fees: Please check all applicable 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 and will be accepted by mail, fax, or email.

EARLY-BIRD OPPORTUNITY* for *Members*	Before APRIL 26, 2004	After APRIL 26, 2004
Member	US $925 ❑	US $1000 ❑
Nonmember		US $1350 ❑
Government Member		US $ 300 ❑
Government Nonmember		US $ 405 ❑
Charitable Nonprofit/Academia (Full-Time), Member		US $ 550 ❑
Charitable Nonprofit/Academia (Full-Time), Nonmember		US $ 745 ❑

**To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.*

Join DIA now to qualify for the member fee, save and receive all the benefits of membership for a full year!

Membership **www.diahome.org/docs/Membership** **US $ 130** ❑

❑ To receive a tabletop exhibit application, please check.

Please check the applicable category below:

❑ Academia ❑ Gov't ❑ Industry ❑ CSO ❑ Student

PAYMENT METHODS ***(Please check payment method):***

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 827192, Philadelphia, PA, USA 19182-7192. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** in the currency of your choice to: PNC Bank, 1600 Market Street, Philadelphia, PA 19103, USA. DIA Account # 8606072742. ABA # 031000053. SWIFTCODE # PNCCUS33. Your name and company, as well as the above meeting I.D. number, must be included on the transfer document to ensure payment to your account.

❑ **CREDIT CARD** number may be faxed to: +1 215 442 6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

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Signature _____

GROUP DISCOUNTS AVAILABLE

Register 3 individuals from the same company location and receive complimentary registration for a 4th! *All 4 individuals must register and prepay at the same time.* 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 enrolled delegates of similar membership status at any time.

Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company location and return them together to DIA.

❑ *Please indicate that this form is part of a group registration by checking this box.*

Please list below the names of the other three registrants from your company location.

1. _____

2. _____

3. _____

Please complete the information below.

Last Name First Name Middle Initial

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Affiliation (Company)

Address

City State Zip Country

(Please write your address in the format required for delivery to your country.)

email

*Telephone Number *Fax Number

*(A Telephone and Fax Number are required for faxed confirmation.)