

# Best Practices and Development of Standards for the Submission of Genomic Data to the FDA

WORKSHOP CO-SPONSORED BY



November 27-28, 2006 | Washington Marriott Hotel, Washington, DC, USA

## PROGRAM COMMITTEE

### FEDERICO GOODSAD, PhD

Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

### BRUCE DAVID CAR, PhD

Executive Director, Discovery Toxicology, Bristol-Myers Squibb

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### DONNA L. MENDRICK, PhD

Scientific Fellow and Vice President, Toxicogenomics Gene Logic, Inc.

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### TARYN ROGALSKI-SALTER, PhD

Director, US Regulatory Policy, Merck Research Laboratories (BIO)

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Computational Chemist, NCTR, FDA

### WEIDA TONG, PhD

Director, Center for Toxicoinformatics, NCTR, FDA

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Vice President, Emerging Markets and Molecular Diagnostics, Research and Development, Affymetrix Inc.

### CHRISTOPHER WEBSTER, PhD, MS

Director, Regulatory Strategy and Intelligence Millennium Pharmaceuticals, Inc. (PhRMA)

## CONTACT INFORMATION

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## OVERVIEW

A Best Practices Document for the Submission of Data in a VGDS is a timely effort both for its content as well as for the discussions and debates it is likely to generate. It summarizes experience gained from the analysis of Voluntary Genomic Data Submissions. It provides a reference document for future voluntary submissions and analyses as well as for discussions at the FDA regarding best practices for submission of genomic data. The document is being drafted through several steps intended to promote extensive review and feedback from experts in each area. Teams of scientists from the FDA have been assembled to work from an initial draft outline. Expert review, particularly from the Interdisciplinary Pharmacogenomics Review Group (IPRG), was received for individual sections and also for the final draft.

An integral part of Best Practices in reference to VGDS genomic data submissions is the work of the MicroArray Quality Control (MAQC) Consortium. The Consortium has been led by scientists from the National Center for Toxicological Research at the FDA. It has worked over the past 18 months on experiments leading to recommendations on standards to improve the reproducibility of gene expression measurements in microarrays. The results of these experiments were captured in papers published in Nature Biotechnology in September/October 2006. These papers include recommendations for analysis of microarray data, correlation of results across replicates, sites and platforms, and validation of microarray results with quantitative platforms.

This two-day symposium includes a series of presentations on topics related to Best Practices and the MAQC Consortium work as well as about the development of other microarray standards. There will also be a number of breakout sessions on best practices and standards in the submission of genomic data. The discussions from these breakout sessions will be extremely useful in the further development of the Best Practices document and future guidances.

## WHO SHOULD ATTEND

▶ Pharmaceutical scientists ▶ Diagnostic scientists ▶ Platform provider scientists

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

- ▶ Discuss the need for Best Practices in the submission and review of genomic data in a VGDS.
- ▶ Identify key areas where these Best Practices impact the adoption of genomic data in drug development and regulatory review.
- ▶ Specify Best Practices that may be drafted from consensus standards for microarray data.

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

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## SUNDAY • NOVEMBER 26

**6:00-8:00 PM**     **REGISTRATION**

## MONDAY • NOVEMBER 27

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

**8:00-8:15 AM**     **WELCOME AND OPENING REMARKS**  
**THE NEED FOR BEST PRACTICES AND  
STANDARDS IN THE SUBMISSIONS OF GENOMIC  
DATA: THE VGDS EXPERIENCE**  
**Federico Goodsaid, PhD**  
Senior Staff Scientist, Genomics Group, Office  
of Clinical Pharmacology, Office of Translational  
Science, CDER, FDA

**8:15-8:45 AM**     **SESSION 1**  
**IMPACT OF VOLUNTARY GENOMIC DATA SUBMISSIONS  
ON REVIEW AND REGULATION IN THE FIELD OF GENOMICS  
AT THE FDA**

CHAIRPERSON

**Felix W. Frueh, PhD**  
Associate Director, Genomics, Office of Clinical Pharmacology,  
Office of Translational Science, CDER, FDA

Approximately two years ago we held the first meeting with a sponsor of a Voluntary Genomic Data Submission (VGDS). Since then, we have received twenty-five submissions and held about twenty meetings. In addition to excellent and cutting-edge science and technology, we have learned about the strategic use of genomics in current drug development efforts and the challenges in the interpretation and conclusions from highly complex data. This presentation will summarize our experience and "lessons learned" and highlight our plans for the future of this exciting program of voluntary submissions.

**8:45-9:15 AM**     **KEYNOTE PRESENTATION**  
**LESSONS LEARNED WITH  
JOINT FDA/EMEA MEETINGS**  
**Eric Abadie, MD, MBA**  
Vice Chairman, CHMP, EMEA, EU  
ICH Steering Committee Member  
Director, AFSSAPS, France

Joint FDA/EMEA VGDS meetings represent a major accomplishment in the collaboration of the FDA and EMEA for the development of policy and procedures for submission of genomic data. The meetings have had an impact both in terms of the scientific background developed from these as well as in the perspective gained for policy decisions regarding the submission of genomic data.

**9:15-10:00 AM**    **PANEL DISCUSSION**

**THE VGDS EXPERIENCE**

CHAIRPERSON

**Christopher Webster, PhD, MS**

Director, Regulatory Strategy and Intelligence  
Millennium Pharmaceuticals (PhRMA Representative)

An experienced, multi-disciplinary panel will discuss the different utilities of and strategies for VGDS submissions within drug development programs. The discussion will seek to highlight the advantages and disadvantages of the process for nonclinical and clinical data, including consideration of the joint EU/US process, and to reach consensus on new data standards.

PANELISTS

**Bruce David Car, PhD**

Executive Director, Discovery Toxicology  
Bristol-Myers Squibb

**Brian Spear, PhD**

Director, Pharmacogenetics  
Abbott Laboratories

**Michael Lawton, PhD**

Drug Safety Research and Development, Pfizer Inc

**George Mulligan, PhD**

Senior Scientist, Millennium Pharmaceuticals, Inc.

**10:00-10:30 AM**    **SESSION 2**

**THE CHALLENGE FOR REPRODUCIBILITY IN GENOMIC MICROARRAY DATA**

CHAIRPERSON

**Janet A. Warrington, PhD**

Vice President, Emerging Markets and Molecular Diagnostics,  
Research and Development, Affymetrix Inc.

Microarray experiments have generated vital research data in academic, government, and industry laboratories over the past decade. Gene expression measurements with these microarrays have generated signatures or lists of genes predicting outcomes associated with the efficacy or safety of drugs. However, periodic reports have surfaced in the scientific literature suggesting that these expression signatures or lists have poor reproducibility. Initiatives driving the development of best practices and standard controls are moving the field forward to ensure demonstrable reproducibility of genomic microarray data.

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

**10:45 AM-12:00 PM**    **SESSION 3**

**BEST PRACTICES IN THE SUBMISSION OF GENOMIC DATA TO THE FDA**

CHAIRPERSON

**Federico Goodsaid, PhD**

Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

The shared VGDS experience between the FDA and the pharmaceutical industry has confirmed the need for a VGDS Best Practices document for the submission of genomic data. These have been

assembled at the FDA with the advice of scientists from the Agency and industry. This session will present the results of this effort.

■ **Study Design**

CLINICAL STUDY DESIGN AND DATA

**Angela Men, PhD**

Pharmacologist, CDER, FDA

MINIMUM STANDARDS FOR NONCLINICAL TOXICOLOGY DATA

**Lilliam Rosario, PhD**

Pharmacologist, CDER, FDA

■ **Genotyping**

METHODS

**Shiew-Mei Huang, PhD, FCP**

Deputy Director for Science, Office of Clinical Pharmacology,  
CDER, FDA

REPORTS

**Maria Chan, PhD**

CDRH, FDA

■ **Proficiency Testing**

PROFICIENCY TESTING

**Laura Reid, PhD**

Director of R&D, Expression Analysis

**12:00-1:00 PM**    **LUNCHEON**

**1:00-2:30 PM**    **SESSION 3 CONTINUED**

■ **Gene Expression**

RNA ISOLATION, HANDLING AND CHARACTERIZATION

**Shashi Amur, PhD**

Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

LABELING REACTIONS

**Michael Orr, PhD**

Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

HYBRIDIZATIONS AND FLUORESCENCE READER SETTINGS

**James Fuscoe, PhD**

Director, Center for Functional Genomics, NCTR, FDA

STATISTICAL CONSIDERATIONS

**Speaker has been invited**

Office of Biostatistics, FDA

NORMALIZATION AND ANALYSIS OF HYBRIDIZATION DATA

**Leming Shi, PhD**

Computational Chemist, NCTR, FDA

BIOLOGICAL INTERPRETATION OF DIFFERENTIALLY EXPRESSED GENES

**Emanuela Lacana, PhD**

Visiting Associate, CDER, FDA

DATA SUBMISSION FORMATTING

**Weida Tong, PhD**

Director, Center for Toxicoinformatics, NCTR, FDA

**2:30-3:00 PM**    **REFRESHMENT BREAK**

**SESSION 4-A**
**ARE WE READY FOR ELECTRONIC DATA SUBMISSION OF GENOMIC DATA TO THE FDA?**

CHAIRPERSON

**Michael Orr, PhD**

Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

This breakout session is going to provide an overview of the ongoing initiatives that are designed to facilitate the electronic submission of nonclinical, clinical, and genomic data to the FDA. The focus will be on identifying the current hurdles for fully realizing the submission of electronic voluntary

genomic data (eVGDS) to the FDA and determining potential paths for efficiently moving this process forward in the future.

**ELECTRONIC DATA SUBMISSIONS AT THE FDA**
**Edward D. Helton, PhD**

Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

**STATUS UPDATE ON HL7 CDISC PGX STANDARDS PROJECT**
**Joyce Hernandez, PhD**

Merck &amp; Co., Inc.

**Stephen E. Wilson, DrPH, CAPT. USPHS**

Director, Division of Biometrics III, CDER, FDA

**Weida Tong, PhD**

Director, Center for Toxicoinformatics, NCTR, FDA

**SESSION 4-B**
**WHAT ARE THE STANDARDS FOR THE REPRODUCIBILITY OF SNP DATA?**

CHAIRPERSON

**Myla Lai-Goldman, MD**

Executive Vice President, Chief Medical Director and CSO, LabCorp

This session will provide an initial overview of the clinical application of SNP assays in pharmacogenetics and clinical trials. The focus will be on identifying the current hurdles for inclusion of SNP assays in the submission of electronic voluntary genomic data (eVGDS) to the FDA. We will be focused on questions such as: what are the assay definitions (sensitivity, specificity, positive/negative predictive value) and platform requirements to determine the clinical utility of

SNPs. Additionally, questions will address the types of genetic variation (SNP, insertion/deletion, haplotypes, etc) and discuss the impact of other factors such as the frequency of variations and penetrance.

**WHOLE GENOME SNP ASSOCIATION SCANS: CLINICAL PGX APPLICATIONS AND STANDARDIZATION**
**Amy Brower, PhD**

Executive Director, Medical Informatics and Genetics, Third Wave Technologies, Inc.

**Eric Lai, PhD**

Vice President, PGx Experimental Project Coordination and Analysis, GlaxoSmithKline

**David L. Barker, PhD**

Vice President and Chief Scientific Officer, Illumina, Inc.

**SESSION 4-C**
**P VS. FC: CONTRIBUTIONS OF SENSITIVITY, SPECIFICITY AND REPRODUCIBILITY IN THE ANALYSIS OF MICROARRAY DATA**

CHAIRPERSON

**Roderick Jensen, PhD**

Alton Brann Distinguished Professor of Physics, Biology, and Mathematics and Director of the Center for Environmental Health, Science, and Technology, University of Massachusetts Boston

The lack of reproducibility between lists of genes identified as differentially expressed from similar or identical study designs with different platforms or laboratories has been used to question the reliability of microarray technology. The MAQC analyses demonstrated that the apparent lack of reproducibility reported in previous studies was likely caused in part by the common practice of ranking genes solely by a statistical significance measure, for example P values derived from simple t-tests, and selecting differentially expressed genes with a very stringent P-value cutoff. When fold change (FC) was used as the ranking criterion, the gene lists became much more repro-

ducible, especially when fewer genes were selected. FC ranking plus a non-stringent P-value cutoff can be used as a baseline practice for generating more reproducible signature gene lists. The FC ranking enhances reproducibility, whereas the P-value cutoff balances sensitivity and specificity. Has the community been chasing the wrong, moving target, P? Is it time to reconsider the critical role of FC?

**Russ Wolfinger, PhD**

Director of Scientific Discovery and Genomics, SAS Institute Inc.

**Wendell Jones, PhD**

Senior Manager, Bioinformatics and Statistics, Expression Analysis Inc.

**Paul K. Wolber, PhD**

Integrating Manager of Microarray Quality, Agilent Technologies, Inc.

**Shawn C. Baker, PhD**

Scientific Product Manager, Gene Expression, Illumina Inc.

**Richard Shippy, PhD**

GE Healthcare

**Earl Hubbel, PhD**

Principal Statistician, Affymetrix Inc.

**SESSION 4-D**
**ESTABLISHING PROCESSES IN THE BIOLOGICAL INTERPRETATION OF DIFFERENTIALLY EXPRESSED GENES**

CHAIRPERSON

**Don Halbert, PhD**

Vice President, Research and Development, Iconix Biosciences

VGDS submissions include analyses of gene expression data by the sponsor and by the FDA that are connected to biological effects of compound treatment. The methods, context, and conclusions of these analyses may be different and can lead to concerns regarding additional experimentation or even

decisions to move forward. This session will start with brief synopses of biological interpretation from VGDS submissions over the year followed by a discussion of best practices in biological interpretation of these submissions.

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Director, Pharmacogenetics, Abbott Laboratories

**Michael Lawton, PhD**

Drug Safety Research and Development, Pfizer Inc

**Patrick J. Wier, PhD**

Vice President, Safety Assessment, GlaxoSmithKline

## SESSION 5-A

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GE Healthcare

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Principal Statistician, Affymetrix Inc.

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Drug Safety Research and Development, Pfizer Inc

**Patrick J. Wier, PhD**

Vice President, Safety Assessment, GlaxoSmithKline

**TUESDAY • NOVEMBER 28**

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

**8:00-8:30 AM WRAP UP FROM DAY 1 BREAKOUT SESSIONS**

**8:30-9:00 AM SESSION 6: KEYNOTE PRESENTATION**

**MICROARRAY STANDARDS**

KEYNOTE PRESENTER

**Donna L. Mendrick, PhD**

Scientific Fellow and Vice President, Toxicogenomics, GeneLogic, Inc.

To ensure the production of high quality microarray data requires multiple QC checks during the processing of biological samples and of the data generated on arrays. This presentation will discuss lessons learned from the profiling of multiple species of tissues and cells on more than 175,000 Affymetrix GeneChip® microarrays.

**9:00-10:00 AM SESSION 7**

**CDISC AND ELECTRONIC DATA SUBMISSIONS**

CHAIRPERSON

**Rebecca D. Kush, PhD**

President, CDISC

The theme of the Day One breakout sessions (4-A and 5-A) "Are we ready for electronic submission of genomic data to the FDA?" will be addressed more formally in this session. The results of a summer pilot that was conducted to determine the best means of providing case report tabulations along with analysis datasets to FDA in eSubmissions will be presented. There will be a presentation by the CDISC LAB Team Leader on where we are with respect to the development, by HL7 and CDISC, of standards for submission of genomics data. A presentation on the current status of eSubmissions for VGDS projects at the FDA will complete the session.

**CDISC SDTM-ADaM PILOT FOR eSUBMISSIONS**

**Edward D. Helton, PhD**

Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

**OVERVIEW ON STANDARDS FOR GENOMICS REPORTING**

**Phil Pochon, PhD**

Covance Laboratory

**CURRENT STATUS OF ELECTRONIC DATA SUBMISSION FOR VGDS PROJECTS AT THE FDA**

**Michael Orr, PhD**

Senior Staff Scientist, Office of Clinical Pharmacology, CDER, FDA

**10:00-10:45 AM SESSION 8**

**EXTERNAL RNA CONTROLS CONSORTIUM**

CHAIRPERSON

**Ernest S. Kawasaki, PhD**

Head, NCI Microarray Facility, NCI Advanced Technology Center, National Cancer Institute, National Institutes of Health

Microarrays have become the most common method for gene expression profiling at the global level, but a lack of standards has hindered the use of this powerful molecular tool. The ERCC was formed to create a set of RNA controls that will be used in all expression profiling systems, a development which can pave the way for a widespread acceptance of array data in basic research as well as in diagnostic and clinical settings.

**WHY DO WE NEED ERCC?**

**Ernest S. Kawasaki, PhD**

Head, NCI Microarray Facility, NCI Advanced Technology Center, National Cancer Institute, National Institutes of Health

**CLSI-MM16**

**Janet A. Warrington, PhD**

Vice President, Emerging Markets and Molecular Diagnostics, Research and Development, Affymetrix Inc.

**EXTERNAL RNA CONTROLS AND REDUCTION IN OUTLIERS**

**Anne Bergstrom Lucas, PhD**

Research Scientist, Microarray Division, Agilent Technologies, Inc.

**10:45-11:00 AM REFRESHMENT BREAK**

11:00 AM-12:45 PM **SESSION 9**

### THE MICROARRAY QUALITY CONTROL (MAQC) CONSORTIUM

CHAIRPERSON

**Yvonne Dragan, PhD**

Director, Systems Toxicology Division, NCTR, FDA

The reproducibility of differentially expressed genes from microarray data is important for its application in drug development and regulatory review. MAQC is an unprecedented, community-wide effort spearheaded by FDA scientists that seeks to address experimentally key issues surrounding the reliability of microarray data. MAQC has brought together 51 academic, government and commercial institutions to assess the performance of seven microarray platforms with two commercially available RNA sample types. These data have been valuable in the development of standards associated with microarray data acquisition and analysis.

#### MAQC IN THE UNIVERSE OF MICROARRAY STANDARDS

**Yvonne Dragan, PhD**

Director, Systems Toxicology Division, NCTR, FDA

#### WHY DO WE NEED AN MAQC? IMPACT ON GENOMICS AT THE FDA

**Felix W. Frueh, PhD**

Associate Director, Genomics, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

#### OVERVIEW OF MAQC

**Leming Shi, PhD**

Computational Chemist, NCTR, FDA

#### RNA SAMPLE TITRATIONS IN MICROARRAY DATA

**NORMALIZATION**

**Richard Shippy, PhD**

GE Healthcare

#### USING REAL TIME PCR FOR MICROARRAY DATA VALIDATION: LESSONS LEARNED AND APPLICATIONS

**Raymond R. Samaha, PhD**

Senior Manager Gene Expression RD, Applied Biosystems

#### CASE STUDY: TOXICOGENOMICS AND THE REPRODUCIBILITY OF MICROARRAY RESULTS

**Lei Guo, PhD**

Research Biologist, NCTR, FDA

12:45-1:15 PM

**BOXED LUNCH DISTRIBUTION**

1:15-2:00 PM

**WORKING LUNCHEON**

#### PANEL DISCUSSION: MICROARRAY STANDARDS

CHAIRPERSON

**Allen Roses, MD, PhD**

Senior Vice President, Genetics Research

GlaxoSmithKline

Microarray standards presented in this Workshop highlight the potential for reliability in the acquisition, analysis and interpretation of data from these platforms. They also underscore what remains to be done to have these standards integrated in applications of microarrays in drug development and regulatory review.

This Panel Discussion will summarize proposals for next steps in the development of standards for the submission of genomic data to the FDA.

PANELISTS

**Rebecca D. Kush, PhD**

President, CDISC

**Ernest S. Kawasaki, PhD**

Head, NCI Microarray Facility, NCI Advanced Technology Center, National Cancer Institute, National Institutes of Health

**Yvonne Dragan, PhD**

Director, Systems Toxicology Division, NCTR, FDA

2:00 PM

**WORKSHOP ADJOURNED**

**TRAVEL AND HOTEL** The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Washington Marriott Hotel is holding a block of rooms at the reduced rate below until November 3, 2006, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

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## BEST PRACTICES AND DEVELOPMENT OF STANDARDS FOR THE SUBMISSION OF GENOMIC DATA TO THE FDA

NOVEMBER 27-28, 2006 (Event ID #06036)

Washington Marriott Hotel, Washington, DC, USA

### HIGHLIGHTS

- Scientific accomplishments showcased in Voluntary Genomic Data Submissions (VGDS) over the past two years
- Consensus from Q&A sessions about the added value of genomic data in regulatory review
- New applications associated with VGDS, including other omic platforms and estimates for the impact of pharmacogenomic information in clinical trials
- Role of VGDS in the Biomarker Qualification Pilot Process
- Best Practices and Development of Standards in the Submission of Genomic Data to the FDA

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

#### CONTACT INFORMATION

**Event information:** Contact Joanne Wallace, Program Manager, at the DIA office by telephone +1-215-442-6180, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org.

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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.

I cannot attend but please keep me informed of DIA's future events.

(requires completion of name, postal address and email address on this form)

#### PAYMENT OPTIONS Register online at [www.diahome.org](http://www.diahome.org) or check payment method

**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.

Visa  MC  AMEX Exp Date \_\_\_\_\_

Card # \_\_\_\_\_

Name (printed) \_\_\_\_\_

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. Payment should be made in US 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.

#### DRUG INFORMATION ASSOCIATION

800 Enterprise Road, Suite 200  
Horsham, PA 19044-3595 USA

**REGISTRATION FORM** Do not remove mailing label. Please return this entire page. **06036**  
PLEASE CONSIDER THIS FORM AN INVOICE

Please check the applicable category:

Academia  Government  Industry  CSO  Student (Call for registration information)

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 \_\_\_\_\_

email Required for confirmation \_\_\_\_\_

Phone Number Fax Number Required for confirmation \_\_\_\_\_