4th Annual FDA/DIA Statistics Forum

Integrating Knowledge in Clinical Development: Meta-analysis, Non-Inferiority, and Related Topics

April 19-21, 2010 Tutorials: April 18, 2010

Marriott Bethesda North Hotel & Conference Center
Bethesda, MD, USA

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

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

Learn About and Assess Current and Emerging Statistical Methodologies and Quantitative Approaches to Developing Safe and Efficacious New Drugs and Biologics.

Pre-Conference Tutorials will be held on April 18, 2010.
Monitor www.diahome.org for details.

Developed by the FDA/CDER Office of Biostatistics and the DIA Statistics Special Interest Area Community

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4th Annual FDA/DIA Statistics Forum
Integrating Knowledge in Clinical Development: Meta-analysis, Non-Inferiority, and Related Topics

April 19-21, 2010 Tutorials: April 18, 2010

Marriott Bethesda North Hotel & Conference Center, Bethesda, MD, USA

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Director, Division of Biometrics III, CDER, FDA

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Vice President, Clinical Biostatistics
Johnson & Johnson Pharmaceutical Research and Development, LLC

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Joan K. Buenconsejo, PhD
Mathematical Statistician
Office of Translational Sciences, CDER, FDA

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Eli Lilly and Company

Jose Pinheiro, PhD
Senior Director, Biostatistics
Johnson & Johnson Pharmaceutical Research and Development, LLC

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Vice President, Biostatistics and Research Decision Sciences - Late Development Statistics
Merck Research Laboratories
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Ram C. Tiwari, PhD
Associate Director, Office of Biostatistics
CDER, FDA

Joachim Vollmar, MS
Executive Consultant
International Clinical Development Consultants LLC

SPECIAL ADVISORS

Robert T. O'Neill, PhD
Director, Office of Biostatistics, CDER, FDA

Sue-Jane Wang, PhD
Associate Director
Adaptive Design and Pharmacogenomics
Office of Biostatistics, CDER, FDA

Henry Shih-Houng Hsu, PhD, MPH
Director, Division of Biostatistics, CBER, FDA

Gregory Campbell, PhD
Director, Division of Biostatistics, CDRH, FDA

The FDA/DIA Forum provides a venue to discuss important statistical issues associated with the development and review of therapeutic drugs and biologics. The meeting is an annual, open dialogue to discuss FDA's issues, initiatives and guidances – emphasizing the statistical and regulatory challenges.

The conference is an opportunity for statisticians, clinicians and other interested professionals from industry, academia, CROs, and government agencies to learn about and assess current and emerging statistical methodologies and quantitative approaches used to develop evidence of the efficacy and safety of new drug and biologic therapeutic products.

Participants will have a unique opportunity to examine their roles in this enterprise and ask the hard questions that need to be answered – to develop appropriate, scientific/regulatory consensus regarding our purpose and process.

FEATURED TOPICS

- FDA Guidance on Non-Inferiority – http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm
- Meta-analysis
  - Best Practices for Safety and Efficacy
  - In Evaluating Cardiovascular Risks
  - In Justifying Non-Inferiority Margins
- Statistics and Comparative Effectiveness Research
- Subgroups and Tailored Therapies
- Modeling & Simulation for Quantitative Decision Making
- Collaboration: The Development and Sharing of Statistical Methodologies and Programs
- Analysis Data Standards for Submission and Communication

Pre-Conference Tutorials will be held on April 18, 2010.
Monitor www.diahome.org for details.

WHO SHOULD ATTEND

- Statisticians in, or consulting for, the biopharmaceutical industry
- Clinicians
- Epidemiologists
- Drug safety professionals
- Regulatory and medical communication scientists

Developed by the FDA/CDER Office of Biostatistics and the DIA Statistics Special Interest Area Community

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CONTINUING EDUCATION

PLEASE MONITOR THE DIA WEBSITE FOR CONTINUING EDUCATION INFORMATION.

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

- . Discuss innovative statistical solutions to issues associated with the evidence and regulatory review of therapeutic drugs and biologics;
- . Describe the application of statistical methodologies and thoughts to the development of new therapeutic biologics and drugs;
- . Explain the impact of regulations and Guidances on statistical practice; and
- . Discuss ideas for improving the communication between industry statisticians and reviewers.

DAY 1 | SUNDAY, APRIL 18

12:30-1:30 PM TUTORIAL REGISTRATION

1:30-4:30 PM TUTORIAL #1

Non-inferiority Clinical Trial without a Placebo Arm

INSTRUCTORS:

H.M. James Hung, PhD
Director, Division of Biometrics I, OB/OTS
CDER, FDA

Sue-Jane Wang, PhD
Associate Director, Office of Biostatistics, OTS
CDER, FDA

Availability of standard of care and ethical considerations among others have generated vested interests in employing an active control treatment for assessing the effect of a test treatment in clinical trials without a placebo arm. The objectives of such an active controlled clinical trial may be in a wide variety: 1) to demonstrate that the test treatment is efficacious through non-inferiority over the active control, 2) to demonstrate that the test treatment is superior to the active control, etc. In addition, such an active controlled trial may involve multiple testing, such as testing superiority and non-inferiority of the test treatment over the control, simultaneously or in a hierarchical order, on a single endpoint or multiple endpoints. Multiple doses may also be involved. This short course will provide an overview of essential design specifications, outline the fundamental issues in design and analysis of active controlled trials and on the challenges in applications for evaluation of drug products, and discuss statistical methodology. Some typical clinical trial examples will be presented for illustrative purposes.

Learning Objectives

This short course is designed to provide essential knowledge about the methodological issues pertaining to clinical trials with an active control treatment. The short course provides a variety of statistical frameworks of inference given in the literature and lays out the fundamental issues and challenges related to the frameworks. They include comparability issues, critical underlying assumptions, defining non-inferiority margin, statistical risks, and interpretability issues. After taking this short course, the attendees are expected to be very familiar with the topics described above.

Target Audience

Master level and PhD level biostatisticians who are heavily engaged in design and analysis of active controlled clinical trials.

1:30-4:30 PM TUTORIAL #2

Meta-analysis

INSTRUCTORS:

Brenda Jean Crowe, PhD
Principal Research Scientist, Global Statistical Sciences
Eli Lilly and Company

Ingram Olkin, PhD
Professor Emeritus
Stanford University

Meta-analysis enables researchers to synthesize the results of a multitude of independent studies to arrive at a combined weight of evidence. Meta-analysis of published literature or of individual patient data is increasingly being used in the regulatory setting to answer safety questions, in the health policy arena, and within companies' drug development programs.

This half-day workshop will begin with an overview of Meta-analysis within the context of medicine and health care for which a Meta-analysis has been published. This will be followed by a discussion of statistical issues and methods, as for example, outcome measures and effect sizes; nonparametric methods; least squares analyses; multiple treatment, outcome, or time point models; treatment of zero cells; binary outcomes for multiple categories; random effects models.

Learning Objectives

At the end of this tutorial, participants should be able to:

- Understand the key principles of Meta-analysis as it relates to medicine and health care
- Discuss alternate statistical methods and understand the uses

Target Audience

This tutorial is designed for Statisticians in, or consulting for, the biopharmaceutical industry, Clinicians, Epidemiologists, Drug safety professionals, and Regulatory and medical communication scientists.

5:00-7:00 PM GENERAL ATTENDEE REGISTRATION

DAY 2 | MONDAY, APRIL 19

7:30–8:45 AM CONTINENTAL BREAKFAST AND ATTENDEE REGISTRATION

8:45–9:00 AM WELCOME AND OPENING REMARKS

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III
CDER, FDA

Barry Schwab, PhD
Vice President, Clinical Biostatistics
Johnson & Johnson Pharmaceutical Research and Development, LLC

9:00–10:00 AM KEYNOTE ADDRESSES

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
FDA

Robert T. O'Neill, PhD
Office of Biostatistics
CDER, FDA

10:00–10:30 AM BREAK

10:30 AM–12:00 PM SESSION 1

Meta-analysis: Setting the Stage

Session Chairpersons:

Hsien Ming (Jim) Hung, PhD
Director, Division of Biometrics I, OB, OTS
CDER, FDA

Christy Chuang-Stein, PhD
Executive Director, Statistical Research and Consulting Center
Pfizer Inc

Armin Koch, PhD
Professor and Head of Institute of Biometry
Hannover Medical School, Germany

Meta analysis is increasingly being used to assess the safety and efficacy of pharmaceutical products. While there is a strong need for adopting good meta analysis principles when conducting such analyses, there is an equally strong need to strike a balance between communications of well-articulated findings and a rush to communicate ambiguous results that could have huge public health implications. In this session, we will hear about this delicate balance and an overview of meta analysis methodology.

Speakers:

Introduction

Christy Chuang-Stein, PhD
Executive Director, Statistical Research and Consulting Center
Pfizer Inc.

Good Meta-analysis Practice

David L. DeMets, PhD
Biostatistics & Medical Informatics
University of Wisconsin

Safely Interpreting the Findings of Meta-analysis

Armin Koch, PhD
Professor and Head of Institute of Biometry
Hanover Medical School, Germany

12:00–1:00 PM LUNCH

1:00–2:30 PM SESSION 2

Meta-analysis to Evaluate Cardiovascular Risk

Session Chairpersons:

Ram Tiwari, PhD
Associate Director, Office of Biostatistics, CDER, FDA

Joachim Vollmar
Executive Consultant
International Clinical Development Consultants LLC

The FDA's recently issued Guidance for Industry on "Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes" requests a prospective meta-analytic approach to analyze cardiovascular events across Phase 2 and Phase 3 controlled clinical trials and explore similarities and/or differences in subgroups. Before submission of the NDA/BLA the incidence of important cardiovascular events occurring with the investigational agent and with the control group are to be compared. This session will describe the clinical perspective of cardiovascular risks, and the basic statistical concepts such as retrospective and prospective meta-analyses and implications. A panel and floor discussion with the speakers of sessions 1 and 2 will follow.

Speakers:

Meta-analysis to Evaluate Safety: Clinical Perspective

Mary H. Parks, MD
Director, Division of Metabolism and Endocrinology
CDER, FDA

Meta-analysis in Assessing Cardiovascular Safety During Development of Diabetes Drugs: Looking Back and Planning Ahead

Jesse A. Berlin, DrSC
Vice President, Pharmacoepidemiology
Johnson & Johnson Pharmaceutical Research & Development, LLC

Integrating Assessment of Glycemic Control and Cardiovascular Safety for Antidiabetic Medications

Armin Koch, PhD
Professor and Head of Institute of Biometry
Hannover Medical School
Germany

2:30–3:15 PM SESSION 3

Panel / Floor Discussion and Question & Answer for Session 1 & 2

Moderators:

Christy Chuang-Stein, PhD
Executive Director, Statistical Research and Consulting Center
Pfizer Inc

Armin Koch, PhD (University of Hannover)
Professor and Head of Institute of Biometry
Hannover Medical School, Germany

Ram Tiwari, PhD
Associate Director for Statisticians
CDER, FDA

Joachim Vollmar
Executive Consultant
International Clinical Development Consultants LLC

This session offers Forum participants an opportunity to ask questions of the speakers in Sessions 1 and 2. In addition, the possibility of using the assessment of cardiovascular risk of anti-diabetic products for type 2 diabetes as a working model to assess other drug-induced injuries will be discussed.

Panelists:

Tsi-Lien Lin, PhD
Mathematical Statistician
CBER, FDA

Mary H. Parks, MD
Director, Division of Metabolism and Endocrinology
CDER, FDA

David L. DeMets, PhD
Biostatistics & Medical Informatics
University of Wisconsin

Hsien Ming (Jim) Hung, PhD
Director, Division of Biometrics I, OB, OTS
CDER, FDA

3:15–3:45 PM BREAK

3:45–5:15 PM SESSION 4

FDA Guidance on Non-Inferiority: An Overview

Session Chairpersons:

Hsien Ming (Jim) Hung, PhD
Director, Division of Biometrics I, OB, OTS , CDER, FDA

George Y. H. Chi, PhD
Senior Director, Statistical Science
Johnson & Johnson Pharmaceutical Research and Development, LLC

In this session, we will look at the salient points in the forthcoming FDA guidance document on non-inferiority trials. We will have a distinguished panel of experts to provide their thoughts on the selected Guidance topics and related questions.

Panelists:

Robert T. O'Neill, PhD
Director, Office of Biostatistics
CDER, FDA

Robert J. Temple, MD
Associate Director, Office of Medical Policy
CDER, FDA

DAY 3 | TUESDAY, APRIL 20

7:30–8:30 AM CONTINENTAL BREAKFAST AND ATTENDEE REGISTRATION

8:30–10:00 AM SESSION 5

Meta Analysis in the Integrated Summary of Efficacy and in Defining a Non-inferiority Margin

Session Chairperson:

Sue-Jane Wang, PhD
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, CDER, FDA

Following the FDA draft guidance on Non-inferiority trials, it has been recognized that one of the important tasks for consideration during the planning of a non-inferiority active controlled trial is defining the non-inferiority margin. The fundamental principle is that the control effect should have been demonstrated via placebo-controlled trials. In this session, we will highlight quantifying the treatment effect via Meta-analysis in two settings: 1) hot to quantify the treatment effect via Meta-analysis as an integrated summary of efficacy prior to any consideration of a future Non-inferiority trial, and 2) how can the Non-inferiority margin be defined when planning a Non-inferiority active controlled trial, when historical controlled trials may or may not be available. The panel discussion will address the issues and caveats with the use of Meta-analysis to quantify the treatment effect and to define the Non-inferiority margin.

Speakers:

Meta Analysis in the Integrated Summary of Efficacy: Prospective Meta-analysis and Other Strategies for Reducing Bias When Integrating Trial Evidence

Robert John Simes, MSc, MD
Director, NHMRC Clinical Trials Centre
The University of Sydney
Australia

Meta Analysis to Assist Margin Decision
Example 1: Meta-analysis to Compare Combination Therapies: A Case Study in Kidney Transplantation

Steffen Witte, PhD
Novartis Pharma AG, Switzerland

Meta Analysis to Assist Margin Decision (ICH E10)
Example 2: Use Heparin Case and Aspirin Case Examples with a Focus on the Extreme Difficulty of Non-Inferiority Margin Definition, The Problem with Random Effect

Hsien Ming (Jim) Hung, PhD
Director, Division of Biometrics I, OB, OTS
CDER, FDA

10:00–10:30 AM BREAK

10:30–12:00 AM SESSION 6 — PANEL DISCUSSION

The Many Facets of Non-inferiority Trials

Session Chairpersons:

George Y. H. Chi, PhD
Senior Director, Statistical Science
Johnson & Johnson Pharmaceuticals Research & Development, LLC

Aloka Chakravarty, PhD
Division Director, Quantitative Safety and Pharmacoepidemiology Group
CDER, FDA

During the panel discussions, we will look at some fundamental questions about the objectives of a non-inferiority trial and the important hypotheses that address these objectives and should be tested. We will discuss other possible approaches and the pros/cons of these alternative approaches when compared with the fixed-margin approach.

Panelists:

Robert T. O'Neill, PhD
Director, Office of Biostatistics
CDER, FDA

Robert J. Temple, MD
Associate Director, Office of Medical Policy
CDER, FDA

James H. Ware, PhD
Director, Biostatistical Science Program
Harvard School of Public Health

Kevin J. Carroll
Chief Statistician
AstraZeneca, United Kingdom

12:00–1:00 PM LUNCH

1:00–2:30 PM SESSION 7

Modeling and Simulation for Quantitative Decision Making in Drug Development

Session Chairpersons:

Yaning Wang, PhD
Team Leader, Pharmacometrics Team
OCP, OTS
CDER, FDA

José Pinheiro, PhD
Senior Director, Biostatistics
Johnson & Johnson Pharmaceutical Research and Development, LLC

The Critical Path Initiative report by the FDA highlighted the low productivity in drug development as measured by the high costs and high risks of failure in the current development processes and the declining number of successful products reaching patients. The report calls for a joint effort of industry, academia, and the FDA to improve the efficiency and likelihood of success of clinical development programs. Among the various strategies being explored, modeling and simulation

(M&S) approaches have received a great deal of attention, being increasingly used for quantitative, data-driven decision making in all phases of drug development. This session will review the use of M&S methods in both the "learn" and "confirm" phases of drug development, discussing its potential advantages and pitfalls over more traditional approaches. Emphasis will be given to applications of M&S approaches in the design and analysis of clinical studies.

Speakers:

Learn-Apply Paradigm: Re-Confirming the Goals of Drug Development

Jogarao V. Gobburu, PhD
Pharmacometrics, Office of Clinical Pharmacology
CDER, FDA

Re-engineer Placebo-Controlled Clinical Trials in Depression Using Model-Based Approach

Roberto Gomeni
Director CPK/M&S
GlaxoSmithKline S.J.A., Italy

Modeling and Simulation in the Analysis of Safety Data from Clinical Trials

Georgina Bermann, PhD
Expert Statistician
Novartis Pharma AG, Switzerland

Panelists:

Leslie A. Kenna, PhD
Senior Scientist, Quantitative Safety and Pharmacoepidemiology
CDER, FDA

Kuang-Kuo Gordon Lan, PhD
Senior Director of Statistical Science
Johnson & Johnson Pharmaceuticals Research & Development, LLC

2:30–3:00 PM BREAK

3:00–5:00 PM SESSION 8

Challenges in Developing Tailored Therapies by Subgroup Identification

Session Chairpersons:

Henry Shih-Houng Hsu, PhD, MPH
Director, Division of Biostatistics
CBER, FDA

Walter W. Offen, PhD
Senior Research Fellow, Global Statistical Sciences
Eli Lilly and Company

Session Co-Organizer:

Stephen Ruberg, PhD
Senior Research Fellow, Global Statistical Sciences
Eli Lilly and Company

In recent years there has been a great deal of research conducted on the development of tailored therapies by prospective use of biomarkers (genotypic or phenotypic — e.g. trastuzumab [Herceptin®] in breast cancer; isosrbide dinitrate/hydralazine HCl [BiDil®] approved only for African Americans). However, there have been and will continue to be treatment paradigms that are found retrospectively, after completion of registration clinical trials, demonstrating dramatically different effect in a subgroup as compared to the complementary subgroup. The issues of how to establish this effect as real and not spurious are significant and important. If the new treatment paradigm results in a product label that indicates this treatment for only the specific subgroup that benefited, in a benefit-risk evaluation, and if truth is that it should rather be indicated for the broad population, then we will have deprived many patients of an effective and safe therapy. On the other hand, if the opposite is true, where the label is broad but the true effects are restricted to the "sensitive" subgroup, then many patients will be needlessly exposed to the treatment which does not have positive benefit-risk.

There are many statistical issues related to this problem. One which will be the focus of this session is identification of the "sensitive" subgroup retrospectively, and how to confirm such a finding in order to control the potential multiplicity issue. We will describe some examples of drugs that have been approved for such a subgroup based on retrospective analyses. Variable selection approaches, such as CART (Classification and Regression Tree) along with extensions or alternative methods, will be described. Finally, this session will include speakers from the FDA to share their concerns in restricting a label based on such retrospective analyses, and for them to provide their ideas of how to approach this important problem.

Speakers:

Stephen Ruberg, PhD
Senior Research Fellow, Global Statistical Sciences
Eli Lilly and Company

Gene Pennello, PhD
Mathematical Statistician, Division of Biostatistics
CDRH, FDA

Scott R. Evans, PhD, MS
Department of Biostatistics
Harvard University

Lei Shen, PhD
Senior Research Scientist, Global Statistical Sciences
Eli Lilly and Company

Panel Moderator:

Walter W. Offen, PhD
Senior Research Fellow, Global Statistical Sciences
Eli Lilly and Company

Panelists:

Henry Shih-Houng Hsu, PhD, MPH
Director, Division of Biostatistics
CBER, FDA

Gene Pennello, PhD
Mathematical Statistician, Division of Biostatistics
CDRH, FDA

Scott R. Evans, PhD, MS
Department of Biostatistics
Harvard University

Lei Shen, PhD
Senior Research Scientist, Global Statistical Sciences
Eli Lilly and Company

Joachim Röhmel
Professor, Bremen Institute for Prevention Research and Social Medicine
Universität Bremen, Germany

Stephen Ruberg, PhD
Senior Research Fellow, Global Statistical Sciences
Eli Lilly and Company

5:15–6:15 PM NETWORKING RECEPTION

DAY 4 | WEDNESDAY, APRIL 21, 2009

7:30–8:30 AM CONTINENTAL BREAKFAST AND ATTENDEE REGISTRATION

8:30–10:30 AM SESSION 9

Using CDISC/ADaM to Create Analysis-ready Datasets

Session Chairpersons:

Joy Mele
Statistician
Office of Translational Sciences
CDER, FDA

Cathleen F Barrows, PhD
Associate Director, Biostatistics and Programming, Neurosciences MDC
GlaxoSmithKline

Standardization of analysis datasets can help to improve the quality of the data submitted for an NDA/BLA with a goal of having fully reviewable data available

on Day 1 of the PDUFA calendar. In this session we will discuss the challenges of creating and using CDISC/ADaM standards from an industry and from a regulatory perspective.

Speakers:

Susan J. Kenny, PhD
Director, Statistical Programming
Inspire Pharmaceuticals

Joy Mele
Statistician
Office of Translational Sciences
CDER, FDA

Wen Zeng, PhD
Mathematical Statistician
CDER, FDA

10:30–11:00 PM BREAK

11:00–12:30 PM SESSION 10

Collaborative Environments for Statistical Methodology Development–The Wiki Way

Session Chairpersons:

Joan K. Buenconsejo, PhD
Mathematical Statistician, Office of Translational Sciences
CDER, FDA

Susan P. Duke
Associate Director, Biostatistics Development Partners
GlaxoSmithKline

This session will discuss recent efforts to establish opportunities for collaboration among statisticians at the FDA, in Industry, and in Academia. Among the new initiatives to be discussed is the establishment of a wiki to be used to share ideas, to discuss statistical approaches to issues in drug development, and to share examples of computer programs and software. A topic of interest will be a discussion of recent efforts to document the most desirable approaches for issues and methods encountered by statisticians in the Pharmaceutical Industry.

Speakers:

FDA Activities

Mat Soukup, PhD
Mathematical Statistician, Office of Translational Science
CDER, FDA

Clinical and Translational Science Award (CTSA)

Mary Banach, PhD, MPH
Analyst
UC Davis

DIA Statistic SIAC Activities

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences
Merck Research Laboratories
Chairperson, DIA Statistics SIAC

12:30–1:30 PM LUNCH

1:30–3:30 PM SESSION 11

Comparative Effectiveness Research

Session Chairpersons:

LaRee A. Tracy, MA, PhD
LCDR USPHS
Team Leader (Act), Division of Biometrics VII
Mathematical Statistician/Epidemiologist
CDER, FDA

Matthew D. Rotelli, PhD
Director - Statistics
Eli Lilly and Company

As part of the $787 billion economic stimulus bill approved by Congress, $1.1 billion is slated for comparative effectiveness research. The goal is to understand which drugs, devices, surgeries, or other medical interventions will be worth it to treat you for whatever ails you. Policy makers, whether government or private, will need to make decisions based on this research. Yet, this research is often incomplete, imperfect, contradictory, or outright misleading. The task of summarizing it, interpreting it, understanding its limitations, and planning to fill its gaps is daunting. However, this is exactly what must be done, in a rigorous and unbiased way. To help solve this information crisis, we need statisticians to get involved. In this session, the discussants will explain the need for comparative effectiveness research, the current regulations and guidelines governing it (or the lack thereof), the state of the science and current initiatives, and ways for statisticians to engage.

Speakers:

Robert J. Temple, MD
Associate Director, Office of Medical Policy
CDER, FDA

Robert T. O'Neill, PhD
Director, Office of Biostatistics
CDER, FDA

Scott Gottlieb, MD
Resident Fellow and Practicing Physician
American Enterprise Institute

Robert Ball, MD, MPH
Director, Office of Biostatics & Epidemiology
CBER, FDA

Panelists:

A. Lawrence Gould, PhD
Senior Director, Scientific Staff
Merck Research Laboratories

Joachim Röhmel
Professor, Bremen Institute for Prevention Research and Social Medicine
Universität Bremen
Germany

Vicki L. Seyfert-Margolis, PhD
Senior Advisor, Science Innovation and Policy
Office of the Commissioner, FDA

3:30–3:35 PM CONCLUDING REMARKS

3:35 PM CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

DIA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

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Integrating Knowledge in Clinical Development: Meta-Analysis, Non-Inferiority, and Related Topics

Event #10008 • Tutorials: April 18 • Workshop: April 19-21, 2010

Marriott Bethesda North Hotel & Conference Center, Bethesda, MD, USA

Contact Information
Event Information: Contact Ellen Diegel at the DIA office by telephone 215.442.6158, fax 215.442.6199 or email Ellen.Diegel@diahome.org.

Registration Fees
Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Industry Fee	US $1400 ❑
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TUTORIALS: SUNDAY, APRIL 18 1:30-4:30 PM

#1 Non-inferiority	US $405 ❑
#2 Meta-Analysis	US $405 ❑

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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. # must be 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 Marriott Bethesda North Hotel & Conference Center is holding a block of rooms at the reduced rate below until March 26, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $179 Double $179

Attendees must make their own hotel reservations. Contact the Marriott Bethesda North Hotel & Conference Center by telephone at +1.301.822.9200 and mention the DIA event. The hotel is located at 5701 Marinelli Road, Bethesda, MD 20852, USA..

CANCELLATION POLICY: On or before APRIL 12, 2010
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.

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.

Please check the applicable category:

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Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

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