Co-sponsored by

DIA Drug Information Association

FDA

1st Annual

FDA/DIA Statistics Forum

March 5-7, 2007 | Doubletree Hotel Bethesda, Bethesda, MD, USA

PROGRAM CHAIRS

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Executive Consultant
European Co-Chairman of the DIA Statistics SIAC

SPECIAL ADVISOR

ROBERT O'NEILL, PhD
Director, Office of Biostatistics
CDER, FDA

Open Forum to Discuss Important Statistical Issues Associated with the Development and Review of Therapeutic Drugs and Biologics

HIGHLIGHTS

- Current and emerging statistical methodologies and quantitative approaches used to develop evidence of the efficacy and safety of new therapeutic drug and biologic products
- Discussion of FDA's "Critical Path" initiative — emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data
- Best practices for developing appropriate, scientific and regulatory consensus

FEATURED SESSIONS

- Adaptive Designs – Regulatory Issues, Concerns and Experience;
- Drug Safety Evaluation to meet the Challenges of 21st Century Expectations – What can the pharmaceutical industry and regulatory agencies do differently?;
- Non-inferiority – Revisited;
- Statistical Graphics; and
- Other high priority issues and "Hot Topics" associated with the development of new drugs and biologics

WHO SHOULD ATTEND

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

Plan to attend

Pre-conference Tutorial
Monday, March 5, 2007

CONTACT INFORMATION
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SIAC

THIS PROGRAM WAS DEVELOPED BY FDA/CDER OFFICE OF BIOSTATISTICS AND THE STATISTICS SPECIAL INTEREST AREA COMMUNITY

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CE Breakdown:

Conference: 286-000-07-016-L04; 13.5 pharmacy contact hours (1.35 CEUs); 13.5 *AMA PRA Category 1 Credits™;* 1.4 IACET CEUs

Tutorial 1: 286-000-07-017-L04; 3.25 pharmacy contact hours (.325); 3.25 *AMA PRA Category 1 Credits™;* .3 IACET CEUs

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

- Explore innovative statistical solutions to issues associated with the evidence and regulatory review of therapeutic drugs and biologics
- Describe the application of statistical methodologies and thought to the development of new therapeutic biologics and drugs
- Assess the impact of regulations and guidance on statistical practice
- Discuss ideas for improving the communication between Industry Statisticians and Reviewers
- Examine the year's statistical and regulatory "highlights"

MONDAY • MARCH 5

7:30-8:30 AM TUTORIAL REGISTRATION

8:30-12:00 PM MORNING TUTORIAL

A refreshment break will take place from 10:00-10:15 AM

Statistical Graphics with R for Clinical Trial Data

Mat Soukup, PhD
Mathematical Statistician, Division of Biometrics III, CDER, FDA

Tutorial Overview

This tutorial focuses on taking advantage of the flexible graphic capabilities of R for visualizing clinical trial data. With the large amount of data collected in clinical trials, it is important to be able to understand and communicate the information contained in the data. One powerful technique for this is the use of statistical graphics. The tutorial will cover basic concepts for constructing and modifying traditional graphs in R, and for creating the newer, information-rich Trellis-type displays. Simple methods of importing data into R from an SAS environment will be discussed. Then, building upon these concepts, more complex graphical techniques are covered, with specific emphasis on clinical trial data. Attention is paid to Good Graphic Principles for effectively conveying the information contained in a vast amount of clinical trial data. This tutorial focuses on the graphics sections of the S Language: Statistical Computing and Graphics course offered at the FDA.

Tutorial Learning Objectives

Upon completion, attendees will know how to (1) summarize large amounts of data from a clinical trial and manipulate it to forms congruent for plotting (2) construct and modify traditional graphics (3) construct and modify Trellis type graphics (4) learn about the grid graphics system, and (5) learn how to extend such concepts to create customized graphs for clinical trial data.

Tutorial Target Audience

Persons responsible for reporting clinical trial results.

12:00-1:30 PM ATTENDEE REGISTRATION

Please Note: Lunch will not be served on Monday.

1:30-1:45 PM WELCOME AND OPENING REMARKS

1:45-3:15 PM **Non-Inferiority Trial Design: State of the Art**

Session Chairpersons:

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

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

This is the first of two sessions revisiting the important topic of non-inferiority trials. This session will provide the background on where we stand with respect to the many issues important to the development of therapeutic drugs and biologics. It will be followed by a second session taking the form of a panel discussion designed to discuss and debate the challenging problems associated with these designs and the next steps towards finding solutions.

When a test treatment is evaluated via a non-inferiority analysis in an active controlled clinical trial without a placebo arm, the analysis would need to rely on use of relevant historical trials to project the effect of the selected active control in the non-inferiority trial setting. At least two classes of statistical methods are proposed in the literature to facilitate such a non-inferiority analysis. In this session, the speakers will revisit the pros and cons of the methods, outline the challenging methodological issues and introduce some new perspectives.

Speakers:

Gang Chen, PhD
Director, Clinical Biostatistics, Centocor Inc.

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

3:15-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM **STATISTICAL METHODOLOGY FOR NON-INFERIORITY CLINICAL TRIALS**

SESSION CHAIRPERSONS:

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

Steven M. Snapinn, PhD
Senior Director, Clinical Development, Global Biostatistics and Epidemiology, Amgen, Inc.

Evaluation of a test treatment via a non-inferiority trial design without a placebo arm relies almost entirely on how to employ some relevant historical data to project the effect of the selected positive control comparator that is applied in the non-inferiority trial at stake. There are many extremely challenging problems with such a design. This panel discussion will be devoted to some of the challenging issues, such as the main objective of a non-inferiority trial, the non-inferiority margin issue, preservation of effect, fixed-margin method versus synthesis method, statistical risks or errors associated with a false assertion, intent-to-treat analysis versus per-protocol analysis, issues of multiplicity with multiple non-inferiority analyses or superiority testing.

PANELISTS:

Ralph B. D'Agostino, Sr., PhD
Professor and Chair, Department of Mathematics and Statistics Boston University
Dave L. DeMets, PhD
Professor and Chair, Department of Biostatistics, University of Wisconsin
H.M. James Hung, PhD
Director, Division of Biometrics I, CDER, FDA
Robert T. O'Neill, PhD
Director, Office of Biostatistics, CDER, FDA
Mark Rothman, PhD
Team Leader, Division of Biometrics V, CDER, FDA
Steven M. Snapinn, PhD
Senior Director, Clinical Development, Global Biostatistics and Epidemiology, Amgen, Inc.
Brian L. Wiens, PhD
Director, Biometrics and Data Management, Gilead Colorado, Inc., Chair of the Biopharmaceutical Section, ASA

TUESDAY • MARCH 6

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

8:30-10:00 AM **FEEDBACK FROM PHRMA ADAPTIVE DESIGNS WORKSHOP 2006**

SESSION CHAIRPERSONS:

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

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

The Adaptive Designs Workshop: Opportunities, Challenges and Scope in Drug Development organized by PhRMA and FDA was held Nov. 13-14, 2006 in North Bethesda, MD, USA. Topics ranged from taxonomy and scope of adaptive designs, adaptive approaches, what are we trying to fix, decision making, implementation, data monitoring committee, regulatory interactions and planning, and the future of adaptive designs. Four breakout sessions had detailed focus on: (1) Procedural & DMC issues in adaptive paradigm, (2) Consideration for adaptation in confirmatory trials, (3) Seamless phase II/III design, and (4) Dose finding.

In this session, PhRMA statistical working groups and initiatives will be introduced. Summary of issues from the above adaptive design workshop will be given, followed by a panel discussion.

SPEAKERS:

Walter Offen, PhD
Senior Research Fellow, Global Statistical Sciences, Eli Lilly and Company
Sue-Jane Wang, PhD
Associate Director, Adaptive Design and Pharmacogenomics Office of Biostatistics, CDER, FDA

PANELISTS:

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
Walter Offen, PhD
Senior Research Fellow, Global Statistical Sciences, Eli Lilly and Company
Michael Krams, MD
Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Pharmaceuticals
Brenda Gaydos, PhD
Research Advisor, Eli Lilly and Company
Additional FDA Panelists have been Invited

10:00-10:30 AM **REFRESHMENT BREAK**

10:30 AM-12:00 PM **INFRASTRUCTURE FOR ADAPTIVE DESIGNS: SPONSOR-INVOLVED MODEL? ISAC-ONLY MODEL? DMC-ONLY MODEL? COMBINATION MODEL?**

SESSION CHAIRPERSON:

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

"VIRTUAL" CO-CHAIR*:

Dave DeMets, PhD
Professor and Chair, Department of Biostatistics & Medical Informatics, University of Wisconsin

Implementation of adaptive clinical trial designs requires special attention to infrastructure, such as proper firewalls and standard operating procedures. Safeguards are necessary to ensure that efficacy and safety data can be objectively collected and analyzed to generate interpretable findings. Maintaining the independence of all parties involved is critical to minimize the added potential for biases that adaptive designs introduce compared to fixed designs. In this session, we will hear about different adaptive design infrastructure choices that aim to preclude manipulation of trial conduct and trial logistics. Panelists will speak from experiences in planning, monitoring, implementing adaptive clinical trials with an emphasis on trial conduct, trial logistics, SOPs, and potential legal concerns.

Each panelist will give a short presentation highlighting their experiences as a DMC member, a CRO statistician or a sponsor-non-project-statistician. A panel discussion will follow these presentations.

PANELIST	ROLE
Jay Herson	a DMC member
Reinhard Eisebitt	a DMC member
Martina Elze	an independent or dependent CRO statistician

Paul Gallo a sponsor-involved statistician
Gregory Golm a sponsor-involved statistician

** Dr. DeMets was a co-organizer of this session, but will not be participating onsite.*

12:00-1:00 PM **LUNCH**

1:00-3:00 PM **FLEXIBLE DOSE DESIGNS**

SESSION CHAIRPERSONS:

Peiling Yang, PhD
Team Leader, Division of Biometrics I, CDER, FDA

Barry Schwab, PhD
Executive Director, Clinical Biostatistics
Johnson & Johnson Pharmaceutical Research and Development, LLC

Optimizing the dose of a study drug to each individual patient often occurs in clinical practice, while fixed dose studies are generally required for obtaining regulatory approval to market a drug. The concept of personalized medicine and clinical practice leads to consideration of when clinical studies could be conducted as flexible dose designs rather than fixed dose designs. In flexible dose designs, patients are typically randomized to either drug or placebo, and the dose is optimized for each patient with respect to benefit-risk, using a specific approach or algorithm on allowable dose changes, which are specified in the protocol.

Flexible dose designs offer improvements in efficiency and cost of clinical research, in part due to a reduction in the number of treatment arms required for the study. However, in flexible dose designs it is difficult to compare specific doses with respect to average efficacy or safety, though dose information can be summarized in alternative ways. Conducting one of the Phase 3 studies as a flexible dose design in an overall program has an added benefit of studying a range of several doses in Phase 3, rather than studying only a single fixed dose as occurs all too often.

This session will have speakers from both industry and FDA discussing the advantages and disadvantages of flexible dose designs. They will discuss diseases where flexible dose designs are in broad use today, where they could be utilized more often, and where they should not be utilized. The session will be composed of presentations followed by a panel discussion and Q&A from the audience.

SPEAKERS:

Walter Offen, PhD
Senior Research Fellow, Global Statistical Sciences, Eli Lilly and Company
Michael Detke, MD, PhD
Medical Director, Eli Lilly and Company
Surya Mohanty, PhD
Senior Director, Biometrics & Clinical Informatics, Johnson & Johnson Pharmaceutical Research and Development, LLC
FDA Discussants have been Invited

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

3:30-5:00 PM **DRUG SAFETY EVALUATION TO MEET THE CHALLENGES OF 21ST CENTURY EXPECTATIONS: WHAT CAN THE PHARMACEUTICAL INDUSTRY AND REGULATORY AGENCIES DO DIFFERENTLY?**

SESSION CHAIRPERSONS:

C. George Rochester, PhD, RAC
Lead Mathematical Statistician, Drug Safety, Office of Biostatistics CDER, FDA

Joachim Vollmar, MS
Executive Consultant, European Co-Chairman of the DIA Statistics SIAC

Regulatory agencies, the pharmaceutical and biotechnology industries, government oversight entities, consumer organizations, health research institutes, and healthcare providers are challenged to think differently about drug safety evaluation in the United States and globally. New thinking in how safety is characterized throughout the lifecycle of a product is needed to provide a comprehensive and coherent structure that supports safe products are marketed. Once marketed the continual monitoring and updating of knowledge regarding the safety of products is needed to restore the credibility of regulatory agencies and pharmaceutical manufacturers. This session will discuss new approaches to address scientific challenges that address good risk assessment, transparency in risk communication, and resources necessary to promote public health.

SPEAKERS:

Jesse A. Berlin, ScD
Vice President, Pharmacoepidemiology, Johnson & Johnson Pharmaceutical Research and Development, LLC
An FDA Speaker has been Invited

PANELISTS:

Jesse A. Berlin, ScD
Vice President, Pharmacoepidemiology , Johnson & Johnson Pharmaceutical Research and Development, LLC
C. George Rochester, PhD, RAC
Lead Mathematical Statistician, Drug Safety, Office of Biostatistics, CDER, FDA
Joachim Vollmar, MS
Executive Consultant, European Co-Chairman of the DIA Statistics SIAC
An FDA Speaker has been Invited

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

WEDNESDAY • MARCH 7

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

8:30-10:00 AM **GRAPHICAL ANALYSIS OF CLINICAL DATA**

SESSION CHAIRPERSONS:

Mat Soukup, PhD
Mathematical Statistician, Division of Biometrics III, CDER, FDA

Alan Hochberg
Vice President, Research
ProSanos Corporation

Statistical graphics can play a key role in understanding and visualizing the vast amount of data collected in a clinical trial, and thus

can be important not only for the drug development team and regulatory authorities, but also for the communication of the information to healthcare providers as well as patients. Graphics can be used for assessing efficacy and safety, and also for communicating risk information to both statisticians and non-statisticians. The key to development of effective graphics is to follow Good Graphical Principles, which results in presentations that can readily convey even complex information to researchers, healthcare providers, and patients. This session will explore the potential uses of graphics in the assessment of safety, the potential for graphics to be used in product labeling, and how graphics can be used in conveying risk information.

SPEAKERS:

Monique Mitchell Turner, PhD
Director, Center for Risk Communication Research, University of Maryland
Richard Heiberger, PhD
Professor, Department of Statistics, Temple University
Joy D. Mele, MS
Team Leader (Acting), Division of Biometrics II, CDER, FDA

10:00-10:30 AM **REFRESHMENT BREAK**

10:30 AM-1:00 PM **OTS AND "THE CRITICAL PATH": THINKING ABOUT OUR PRIORITIES, PROGRESS, INNOVATIONS AND NEXT STEPS**

SESSION CHAIRPERSONS:

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

Russ Helms, PhD
Vice President, Technology, Rho, Inc.
North American Co-Chairman of the DIA Statistics SIAC

In May of 2006, under the leadership of Dr. Steven Galson, FDA's Center for Drug Evaluation and Research (CDER) created a new "super office" to lead and support the "Critical Path" vision for innovation in the science and review of new therapeutic products – The Office of Translational Science (OTS). OTS brings together, for the first time, the scientists and resources of the Office of Biostatistics (OB) and the Office of Clinical Pharmacology (OCP). OB and OCP are charged with identifying opportunities for innovation and developing approaches to improve the scientific and review processes associated with the development of new therapeutic drugs and biologics. This session will be an opportunity to hear from OTS leadership who are charged with "thinking about" statistical issues (e.g., multiplicity and missing data) and how we can collaboratively innovate to improve our Science and Review.

SPEAKERS:

Thomas Permutt, PhD
Director (Acting), Division of Biometrics II, CDER, FDA
Mohammad F. Huque, PhD
Director, Division of Biometrics III, CDER, FDA
Robert Powell, PharmD
Associate Director, Office of Translational Sciences, CDER, FDA

1:00 PM MEETING ADJOURNS

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.
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1st Annual FDA/DIA Statistics Forum

Event ID #07008
Doubletree Hotel Bethesda
Bethesda, MD, USA
MARCH 5-7, 2007

HIGHLIGHTS

- Current and emerging statistical methodologies and quantitative approaches used to develop evidence of the efficacy and safety of new drug and biologic therapeutic products
- Discussion of FDA's "Critical Path" initiative — emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data
- Best practices for developing appropriate, scientific and regulatory consensus

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TUTORIAL REGISTRATION

Statistical Graphics with R for Clinical Trial Data

8:30 am-12:00 pm	US $ 350 ❑

CANCELLATION POLICY: On or before FEBRUARY 27, 2007

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.

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