SAVE THE DATE!

4th Annual FDA/DIA Statistics Forum

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

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

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SPECIAL ADVISOR

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

WHO SHOULD ATTEND

- Statisticians
- Clinicians
- Epidemiologists
- Drug safety professionals
- Regulatory and medical communication scientists

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

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

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 intended to be an annual, open dialogue to discuss FDA's issues, initiatives and guidance – 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.

We use this opportunity to come together annually in the Washington, DC area to describe important issues, discuss solutions and review progress and problems. We feel that it is important for all stakeholders 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.

In recent years, thought leaders from government agencies, industry, and academia have discussed:

- Biomarker development and assessments
- Considerations for specific Guidances, including those for Adaptive Design, Non-inferiority, Multiplicity and Missing Data;
- Statistical challenges in analyzing safety data such as meta-analytic methods, analysis of rare adverse events, and multiplicity;
- Current and emerging statistical methodologies and quantitative approaches used to develop evidence of the efficacy and safety of new therapeutic products;
- FDA's "Critical Path" initiative and the 2007 Food and Drug Administration Amendments Act – emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data and the need for new statistical thinking;
- Best practices for developing appropriate, scientific and regulatory consensus;
- The impact of regulations and Guidances on statistical practice;
- Ideas for improving the communication between Industry Statisticians and Reviewers; and,
- The previous year's statistical and regulatory "highlights."

Now is the time to mark your calendars and plan to join us for the 2010 FDA/DIA Statistics Forum!

For Continuing Education Information, please check the DIA website for details.

Developed by the FDA/CDER Office of Biostatistics and the DIA Statistics SIAC

Co-sponsored by FDA | DIA® www.diahome.org

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.

4th Annual FDA/DIA Statistics Forum

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 ❑
Join DIA now to save on future events and to receive all the benefits of membership. Visit www.diahome.org/Membership	MEMBERSHIP US $140 ❑
Discount Fees	
Government (Full-time)	US $ 420 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 700 ❑

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.

PAYMENT OPTIONS: Register online at **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.

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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.

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:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student
(Call for registration information)

Last Name _____

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** _____