DIA

DIA/FDA Biostatistics Industry and Regulator Forum

Short Courses: April 23 | Forum: April 23-25

Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM CO-CHAIRS

Dionne Price, PhD
Acting Deputy Director, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Cristiana Mayer, PhD
Scientific Director, Statistical Modeling and Methodology, Statistics and Decision Science
Janssen Research and Development LLC

PROGRAM COMMITTEE

Mouna Akacha, PhD
Statistical Methodologist
Novartis Pharma AG, Switzerland

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Nevine Zariffa
Vice President and Head Biometrics and Information Sciences
AstraZeneca Pharmaceuticals

Overview

The DIA/FDA *Biostatistics Industry and Regulator Forum* is a collaboration by DIA and FDA. We have focused this event on statistical thinking to inform policy, regulation, development, and review of medical products in the context of the current scientific and regulatory environments including pharmaceuticals, biologics and biosimilars, combination products and devices, and generics. Each session will be co-chaired by an FDA/Industry team working side-by-side with today's experts to present a 360-degree perspective of statistical design, analysis, and methodological approaches to building evidence for pharmaceutical, biologic and biosimilar, combination product and device development, and approval.

Highlights

- Two interactive preconference short courses
- Co-sponsored with the FDA
- Town Hall: An open discussion lead by an expert panel of leaders from industry and regulatory agencies
- Poster Presentations from researchers across the statistics field
- Luncheon Round Table Discussions on cutting-edge topics with key thought leaders
- DIA Statistics Open Community Meeting

Who Should Attend?

Professionals involved in:

- Biostatistics
- Pharmaceutical Development
- Clinical Pharmacology
- Health Economy
- Epidemiology
- Regulatory
- Academia
- Government

Schedule At-A-Glance

DAY ONE | MONDAY, APRIL 23		ROOM
7:30AM-5:35PM	Registration	Foyer C
8:30AM-12:00PM	**Short Course 1:** Artificial Intelligence, Machine Learning, and Precision Medicine **Short Course 2:** Causal Inference: Weighting Methods and Case Studies	Forest Glen Glen Echo
1:00-1:30PM	**Welcome and Opening Remarks**	Salon A-C
1:30-2:30PM	**Keynote Address**	Salon A-C
2:30-3:45PM	**Session 1:** PDUFA VI Pilot Programs: Overview and Expectation	Salon A-C
3:45-4:05PM	Refreshment and Networking Break	Salon D
4:05-5:35PM	**Session 2:** Complex Innovative Designs	Salon A-C
5:35-6:35PM	Stats Community Open Meeting	Forest Glen
DAY TWO | TUESDAY, APRIL 24		**ROOM**
7:30AM-5:00PM	Registration	Foyer C
7:30-8:30AM	Continental Breakfast and Networking	Salon D
8:30-8:35AM	**Welcome and Opening Remarks**	Salon A-C
8:35-10:05AM	**Session 3:** Challenges and Opportunities with Drug Development in Alzheimer's Disease	Salon A-C
10:05-10:30AM	Refreshment and Networking Break	Salon D
10:30AM-12:00PM	**Session 4:** Bridging the Gap: RWE and RCT	Salon A-C
12:00-1:30PM	Luncheon and Round Table Discussions	Salon D
1:30-3:00PM	**Session 5:** The Use of Patient Experience Data to Inform Benefit- From Instrument to Label Claim	Salon A-C
3:00-3:30PM	Refreshment and Networking Break	Salon D
3:30-5:00PM	**Session 6:** Identical Cousins: Generics and Biosimilars	Salon A-C
5:00-6:00PM	Poster and Networking Reception	Veranda
DAY THREE | WEDNESDAY, APRIL 25		**ROOM**
7:30AM-4:15PM	Registration	Foyer C
7:30-8:30AM	Continental Breakfast and Networking	Salon D
8:30-8:35AM	**Welcome to Day Three**	Salon A-C
8:35-10:05AM	**Session 7:** The Future is Now	Salon A-C
10:05-10:30AM	Refreshment and Networking Break	Salon D
10:30AM-12:00PM	**Session 8:** Risk-Based Monitoring	Salon A-C
12:00-1:30PM	Luncheon and Networking	Salon D
1:30-3:00PM	**Session 9:** ICH Guidances from a Global and Regional Perspective	Salon A-C
3:00-4:15PM	**Session 10:** Senior Leaders (FDA and Industry) Town Hall	Salon A-C

Learning objectives

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

- Describe the history and key statistical issues of bioequivalence studies
- Identify the main features of biosimilar drug development and the concept of "switchability" between the innovator biologic and its biosimilar
- Explain the role of the 21st Century Cures Act in enabling the inclusion of patient experience endpoints in drug development
- Assess the process for identifying and developing measures of patient experience
- Examine the role of COA office in regulatory acceptance of patient experience endpoints
- Evaluate how these data are evaluated in the FDA review process
- Define what loss in outcome ascertainment sensitivity we are willing to live with in a RWE study, state if that answer is different for a PCT vs an Obs study
- Describe when one should consider a combination of RCT/PCT/Observational studies
- Formulate scenarios to be considered when using Obs Studies, considering RCT/PCT's are not ethical to perform

Continuing Education

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As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.9 CEUs for this forum. Participants must attend the entire forum (and/or short course) in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

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DAY ONE | MONDAY, APRIL 23

7:30AM-5:35PM

Registration

8:30AM-12:00PM

*Short Courses require a separate registration fee

Short Course 1: Artificial Intelligence, Machine Learning, and Precision Medicine

Instructor

Haoda Fu, PhD
Senior Research Scientist
Eli Lilly and Company

Gain an overview of statistical machine learning and artificial intelligence techniques with applications to precision medicine, in particular to deriving optimal individualized treatment strategies for precision medicine. This course will cover both treatment selection and treatment transition. Instructors will cover logistic regression, support vector machine (SVM)-learning, robust SVM, and angle-based classifiers for multi-category learning, and will show how to modify these classification methods into outcome-weighted learning algorithms for precision medicine. The second part of this course will cover treatment transition. Algorithms, including dynamic programming for Markov Decision Process, temporal difference learning, SARSA, Q-Learning algorithms, and actor-critic methods, will be covered. We will discuss on how to use these methods for developing optimal treatment transition strategies. The techniques discussed will be demonstrated in R.

Learning Objectives

At the conclusion of this short course, participants should be able to:

- Discuss how statistical machine learning and artificial intelligence techniques derive optimal individualized treatment strategies for precision medicine
- Apply statistical machine learning techniques to address problems in personalized medicine and other biomedical applications

Short Course 2: Causal Inference: Weighting Methods and Case Studies

Instructors

Hana Lee, PHD
Mathematical Statistician,
Office of Biostatistics,
Division of Biometrics VII
CDER, FDA

Joo-Yeon Lee, PhD, MA
Senior Mathematical Statistician,
Office of Biostatistics, Division of
Biometrics VII
CDER, FDA

Laine Thomas, PhD
Assistant Professor of Biostatistics
and Bioinformatics
Duke University, Department of
Biostatistics and Bioinformatics

Inverse probability weighting (IPW) methods offer powerful and flexible approaches useful in comparative safety and efficacy studies. This course will start with a general overview on causal inference methods using weighting and a case-study using IPW method, then instructors will introduce recently developed methodology of overlap weights, which places emphasis on clinical equipoise and has statistical advantages over IPW. Simulated data and R code will be provided to demonstrate practical issues of implementation.

Learning Objectives

At the conclusion of this short course, participants should be able to:

- Translate study questions into a causal inference framework using weighting to control for confounding
- Use best practices of weighting methods to a causal inference problem
- Weigh pros and cons of different weighting methods to a causal inference problem

1:00-1:30PM

Welcome and Opening Remarks

Sudip Parikh, PhD
Senior Vice President and Managing Director, Americas
DIA

1:30-2:30PM

Keynote Address

Session Chair

Jacqueline A. Corrigan-Curay, JD, MD
Director, Office of Medical Policy
CDER, FDA

Keynote Speaker

Lisa M. LaVange, PhD
Professor and Chair, Department of Biostatistics, Gillings School of Global Public Health
University of North Carolina at Chapel Hill

DAY ONE | MONDAY, APRIL 23

2:30-3:45PM

Session 1: PDUFA VI Pilot Programs: Overview and Expectation

Session Co-Chairs

Dionne Price, PhD
Acting Deputy Director, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Cristiana Mayer, PhD
Scientific Director, Statistical Modeling and Methodology, Statistics and Decision Science
Janssen Research and Development LLC

As the landscape of drug development evolves, we are faced with new and different challenges. Consequently, the PDUFA VI goals letter outlines several commitments designed to identify and develop strategies to address these challenges. The commitments include the launch of two distinct pilot programs. Speakers in this session will provide a brief overview and highlight key aspects of the CID pilot as well as the MIDD pilot. A panel discussion will follow to expand on expectations from industry and regulators.

Dionne Price, PhD
Director, Division of Biometrics IV, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

PDUFA VI Pilot Programs: Overview and Expectation for Model-Informed Drug Development (MIDD)
Issam Zineh, PharmD, MPH, FCP, FCCP
Director, Office of Clinical Pharmacology, Office of Translational Sciences
CDER, FDA

Panelists

Stuart Bailey
Vice President - Early Development and Discovery Biostatistics
Novartis Institutes For Biomedical Research, Inc.

Jose C. Pinheiro, PhD
Head of Statistical Modeling and Methodology, SDS

3:45-4:05PM

Refreshment and Networking Break

4:05-5:35PM

Session 2: Complex Innovative Designs

Session Co-Chairs

Min Annie Lin, PhD
Mathematical Statistician
CBER, FDA

Amy Xia, PhD
Executive Director, Biostatistics
Amgen, Inc.

Both the 21st Century Cures Act and the PDUFA VI legislations emphasize on complex innovative designs, which require simulations to understand the design operating characteristics, statistical properties, and operational features. This session will review and discuss the issues related to any complex trial design that we need to simulate the trial to understand its full behavior. Additionally, speakers will discuss analyses that are complex enough so that we likely need simulation for deeper understanding of the models. Examples of complex analyses include using hierarchical analyses and historical data will be given. Speakers and panelists will discuss opportunities and challenges relative to complex innovative designs and analyses in medical product development.

Complex Clinical Trials: Design and Analysis
Scott Berry, PhD
President and Senior Statistical Scientist
Berry Consultants LLC

Simulations for Clinical Trial Operating Characteristics
John Scott, PhD
Acting Director, Division of Biostatistics, OBE
CBER, FDA

Panelists

Brian Hobbs, PhD
Associate Staff of Quantitative Health Sciences, The Section Head of C
The Taussig Cancer Institute at Cleveland Clinic

Karen Lynn Price, PhD, MA
Senior Research Advisor
Eli Lilly and Company

5:35-6:35PM

DIA Statistics Community - Open Meeting

DAY TWO | TUESDAY, APRIL 24

7:30AM-5:00PM

Registration

7:30-8:30AM

Continental Breakfast and Networking

8:30-8:35AM

Welcome and Opening Remarks

Session Co-Chairs

Dionne Price, PhD
Director, Division of Biometrics IV, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Cristiana Mayer, PhD
Scientific Director, Statistical Modeling and Methodology, Statistics and Decision Science
Janssen Research and Development LLC

DAY TWO | TUESDAY, APRIL 24

8:35-10:05AM

Session 3: Challenges and Opportunities with Drug Development in Alzheimer's Disease

Session Co-Chairs

Karen Lynn Price, PhD, MA
Senior Research Advisor
Eli Lilly and Company

Kun Jin, PhD
Statistical Team Leader, Office of Biostatistics,
Office of Translational Sciences
CDER, FDA

Alzheimer's disease (AD) represents a huge unmet medical need, and currently there are no therapies for prevention, cure, or to slow progression of disease. The disease is slow to progress and difficult to measure, yielding challenging clinical trial designs that are resource-intensive and have a high risk of failure. Statisticians have an opportunity to be leaders in the improvement of the design and analysis of AD clinical trials and we need to take action now. This session will focus on an open discussion and idea generation regarding what statisticians can do to help address key challenges with AD drug development, to ultimately help bring much needed treatments to patients and their families. In addition, there will be a robust panel discussion, which will incorporate FDA representatives, to hear the regulatory perspective on challenges and opportunities. The session will include ample time for open discussion of ideas, experiences from practice, and key opportunities to better enable statistics to play a key role in moving forward the development of effective therapies for AD.

Alzheimer's Disease: Challenges in Clinical Trial Design, Conduct, and Interpretation
Jamie Mullen, MD
Global Clinical Leader
AstraZeneca

Brief Overview of ASA Biopharmaceutical Section AD Scientific Working Group
Hong Liu-Siefert, PhD
Senior Research Advisor
Eli Lilly and Company

Kun Jin, PhD
Statistical Team Leader, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Panelists

Robert Lenz, MD, PhD
Vice President, Head, Center for Design and Innovation
Amgen

Stephen Wilson, DrPH, MPH
Statistical Consultant

10:05-10:30AM

Refreshment and Networking Break

10:30AM-12:00PM

Session 4: Bridging the Gap: RWE and RCT

Session Co-Chairs

Frank W. Rockhold, PhD, MSc
Professor of Biostatistics
Duke Clinical Research Institute, Duke University Medical Center

Mark Levenson, PhD
Director, Division of Biometrics VII, Office of Biostatistics
CDER, FDA

There is currently a drive and energy behind the use of "big data" and "real-world data". There are three main motivations: Use of RWE data are viewed as 1) a quicker and less expensive approach to clinical development, 2) a way to answer questions of how treatments are or will be used in the real world, and 3) where randomized trials are not ethically possible. We will restrict the discussion to studies done post-approval of the first indication as "RWE" is a non-sequitur for an unapproved drug.

Randomized Pragmatic Clinical Trials: A Potential Bridge Between "RCTs" and "RWE" Studies?
Frank Rockhold, PhD, MSc
Professor of Biostatistics
Duke Clinical Research Institute,
Duke University Medical Center

Statistical Considerations for Pragmatic Cluster Randomized Trial Design
Hrishikesh Chakraborty
Associate Director
Duke Clinical Research Institute, Duke University

Bridging the Gap: Better Use of RWE for Decision-Making from an Industry Perspective
Douglas E. Faries, PhD
Research Fellow
Eli Lilly and Company

Using Healthcare Databases To Evaluate The Safety And Effectiveness Of Newly Marketed Medications
Jessica Franklin, PhD
Assistant ProfessorBrigham and Women's Hospital and Harvard Medical School

12:00-1:30PM

Luncheon and Round Table Discussions

1:30-3:00PM

Session 5: The Use of Patient Experience Data to Inform Benefit- From Instrument to Label Claim

Session Co-Chairs

Jonathan Haddad, MPH
Director, Clinical Statistics
GlaxoSmithKline

Scott Komo, DrPH
Mathematical Statistician, Office of Translational Sciences
CDER, FDA

This session will cover the development and use of patient experience data under the framework established by the 21st Century Cures Act. Through the use of examples, speakers will examine the steps and requirements to establish usable patient experience endpoints and examine how these data are analyzed and used to inform the benefit-risk assessment in the US drug approval and labeling process.

Incorporating Patient Preferences into Regulatory Decision-Making
Telba Irony, PhD
Deputy Director, Office of Biostatistics and Epidemiology
CBER, FDA

Characterizing Patient Experience Endpoints with Patient Reported Outcomes
Josephine Park, MBA, MPH
Director, Patient Centered Outcomes
GlaxoSmithKline

Panelist

Laura Lee Johnson, PhD
Director (Acting), Division III, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

3:00-3:30PM

Refreshment and Networking Break

DAY TWO | TUESDAY, APRIL 24

3:30-5:00PM

Session 6: Identical Cousins: Generics and Biosimilars

Session Co-Chairs

Mouna Akacha, PhD
Statistical Methodologist
Novartis Pharma AG, Switzerland

Jingyu (Julia) Luan, PhD
Lead Mathematical Statistician, Division of Biometrics VIII, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

This session will discuss similarities and differences in the statistical evaluation of generic drugs and biosimilars. It will include two presentations followed by a panel discussion. The first presentation will show the history and statistical issues for bioequivalence studies and the second will discuss bioequivalence and biosimilarity evaluations. Panelists will discuss recent developments in these fields in light of the new initiatives and impact of GDUFA II.

Some History and Statistical Issues for Bioequivalence Studies
Donald Schuirmann, MS
Division of Biometrics VIII, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

A Brief Introduction to Biosimilar Drug Development
Byron Jones
Professor, Executive Director/Senior Biometrical Fellow
Statistical Methodology and Consulting Group,
Novartis Pharma AG, Switzerland

Panelists

Stella Grosser, PhD
Division Director,
Office of Biostatistics,
Office of Translational Sciences
CDER, FDA

John Peters, MD
Deputy Director, Office of Generic Drugs
CDER, FDA

Shein-Chung Chow, PhD
Associate Director, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Thomas Gwise, PhD
Deputy Division Director, Division of Biometrics V
CDER, FDA

Larry Gould, PhD
Senior Director, Scientific Staff
Merck Research Laboratories

5:00-6:00PM

Poster and Networking Reception

DAY THREE | WEDNESDAY, APRIL 25

7:30AM-4:15PM

Registration

7:30-8:30AM

Continental Breakfast and Networking

8:30-8:35AM

Welcome to Day Three

8:35-10:05AM

Session 7: The Future is Now

Session Co-Chairs

Rima Izem, PhD
Lead Mathematical Statistician
Division of Biometrics VII, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Pandu Kulkarni, PhD
Vice President, Biometrics and Advanced Analytics
Eli Lilly and Company

Artificial intelligence and machine learning have achieved great successes in many fields such as text mining, image and voice recognition, and are changing our lives. The use of these methods could revolutionize pharma and healthcare. Statisticians are in a great position to provide leadership in this area by (a) ensuring methodologies are fit for purpose, (b) developing reliable training sets, and (c) accounting for variability and uncertainty associated with multiple data sources. In this session, key opinion leaders from industry, academia, and regulatory will share their thoughts and visions, and their journey on using machine learning and artificial intelligence in the healthcare industry.

Haoda Fu, PhD
Senior Research Scientist
Eli Lilly and Company

Sherri Rose, PhD
Associate Professor of Biostatistics
Department of Health Care Policy,
Harvard Medical School

Panelist
Henry "Skip" Francis
Director, Data Mining and Informatics Evaluation and Research, Office of Translational Sciences
CDER, FDA

10:05-10:30AM

Refreshment and Networking Break

DAY THREE | WEDNESDAY, APRIL 25

10:30AM-12:00PM

Session 8: Risk-Based Monitoring

Session Co-Chairs

Nevine Zariffa
Vice President and Head Biometrics and Information Sciences
AstraZeneca Pharmaceuticals

Mat Soukup, PhD
Deputy Division Director, Division of Biometrics VII, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

The recent ICH E6 now includes explicit recognition that centralized monitoring can/should be part of the quality system for trials with the aim of identifying missing data, inconsistencies, outliers, and a lack of variability. The use of statistics is encouraged to identify trends, looking at the range and consistency of data across sites. The current approach of 100% source data verification would thus be replaced by these newer contemporary techniques. While the principles are clear, implementation requires careful consideration and expert trialists have different views. The session will explore some of the key challenges in fully embedding risk-based monitoring.

Kevin J. Anstrom, PhD
Associate Director of Biostatistics
Duke Clinical Research Institute

Martin Landray, MB, ChB, PhD, FRCP
Professor
University of Oxford,
United Kingdom

Panelists

Eric Genevois-Marlin, MSc
Vice President, Biostatistics and Programming
Sanofi R&D, France

Timothy Rolfe
Director, Risk Based Monitoring, QSci Clinical Statistics (UK), RD Projects
Clinical Platforms and Sciences
GlaxoSmithKline

Jennifer Schumi, PhD, MS
Statistical Science Director
AstraZeneca Pharmaceuticals LP

Martin Landry, MB, ChB, PhD, FRCP
Professor
University of Oxford,
United Kingdom

12:00-1:30PM

Luncheon and Networking

1:30-3:00PM

Session 9: ICH Guidances from a Global and Regional Perspective

Session Co-Chairs

Aloka Chakravarty, PhD
Acting Deputy Director, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

William Wang, PhD
Executive Director, Clinical Safety Statistics, Biostatistics and Research Decision Sciences (BARDS)
Merck Research Laboratories

This session will examine a few ICH regulatory guidances, looking at them both from global and regional perspectives. These guidances may include the recently published ICH E9 R1 step 2b draft, the soon-to-be-published ICH E17, and the upcoming ICH E6/E8 renovation.

We will prepare a case-study scenario for the panelists, then will let panelists develop their own estimands in advance, which they will present briefly and subsequently defend during the panel discussion. We will further introduce additional complexities by different intrinsic/extrinsic factors and critical quality factors across region. This will lead to the discussion of E9 R1, E17, and E6/E8 in an implementation setting.

Mouna Akacha, PhD
Statistical Methodologist
Novartis Pharma AG, Switzerland

Thomas J. Permutt, PhD
Associate Director for Statistical Science and Policy, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Panelists

An Overview of Regulatory Statistics in China
Xiang GUO, PhD
Executive Director, Biometrics
Beigene

Toshimitsu Hamasaki, PhD, MS
Director of Data Science
National Cerebral and Cardiovascular Center, Japan

Devan Mehrotra, PhD
Senior Director, Biostatistics Department
Merck Research Laboratories

3:00-4:15PM

Session 10: Senior Leaders (FDA and Industry) Town Hall

Session Co-Chairs

Dionne L. Price, PhD
Director, Division of Biometrics IV, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

Cristiana Mayer, PhD
Scientific Director, Statistical Modeling and Methodology, Statistics and Decision Science
Janssen Research and Development LLC

Welcome to the Town Hall! Dedicated to sharing the latest information on new guidances, this session will allow open discussion between the audience and an esteemed panel of regulatory and industry experts. Questions asked from the audience may focus on sessions held during the forum, but can also branch out into other areas of regulatory statistics. Panelists will address questions posed by attendees live from the Town Hall as well as those submitted throughout the forum.

Panelists

Jose C. Pinheiro, PhD
Senior Director, Quantitative Decision Strategies
Janssen Research & Development, LLC

Nevine Zariffa
Vice President and Head, Biometrics and Information Sciences
AstraZeneca Pharmaceuticals

John Scott, PhD
Acting Director, Division of Biostatistics, OBE
CBER, FDA

Pandurang Kulkarni, PhD
Vice President, Global Biometrics and Advanced Analytics
Eli Lilly and Company

Ram Tiwari, PhD
Director, Division of Biostatistics, CDRH
FDA

Aloka Chakravarty, PhD
Acting Director, Office of Biostatistics, Office of Translational Sciences
CDER, FDA

4:15PM

Forum Adjourned