DIA

DIA/FDA Biostatistics Industry and Regulator Forum

Short Course: March 16 | Short Course: March 21 | Short Course: March 23
Virtual Event: March 29-31

This Forum is Co-sponsored with the FDA!

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PROGRAM CO-CHAIRS

Fairouz Makhlouf, PhD
Deputy Director
Office of Biostatistics, Office of Translational Science, CDER
FDA

Satrajit Roychoudhury, PhD
Senior Director, Statistical Research and Innovation
Pfizer, Inc.

PROGRAM COMMITTEE

Anup Amatya, PhD
Lead Mathematical Statistician
FDA

Hye Soo Cho, MS
Statistical Analyst
FDA

Mallorie Fiero, PhD
Master Mathematical Statistician, CDER
FDA

Shanti Gomatam, PhD, MS, MSc
Mathematical Statistician
FDA

Lisa Hampson, PhD
Senior Director, Advanced Methodology & Data Science
Novartis Pharma AG, Switzerland

Karen Higgins, PhD
Supervisory Mathematical Statistician
FDA

Dalong Patrick Huang, PhD
Lead Mathematical Statistician, CDER
FDA

Lisa Renee Bailey Iacona, PhD, MPH
Vice President, Oncology Biometrics
AstraZeneca Pharmaceuticals LP

Xiang Ling, PhD
Mathematical Statistician, CDER
FDA

Jerald Schindler, DrPH
Vice President, Enterprise Biostatistics
Medtronic

Venkat Sethuraman, PhD, MBA, MS
Senior Vice President, Global Biometrics and Data Sciences
Bristol Myers Squibb

Guoxing Soon, PhD
Lead Mathematical Statistician
FDA

Li Wang, PhD
Senior Director, Head of Statistical Innovation
AbbVie

Yun Wang, PhD
Deputy Division Director
FDA

Lisa Wruck, PhD
Associate Professor of Biostatistics & Bioinformatics
Duke University

PROGRAM ADVISORS

Brenda Crowe, PhD
Associate Vice President, Statistics
Eli Lilly and Company

Stella Grosser, PhD, MS
Division Director, Office of Biostatistics, OTS, CDER
FDA

Overview

The 17th Annual *DIA/FDA Biostatistics Industry and Regulator Forum* is a unique forum addressing the statistical issues associated with the development and review of therapeutic drugs, biologics, devices, and other medical products. As an open forum to discuss timely topics of mutual theoretical and practical interest to statisticians and clinical trial professionals, this meeting focuses on the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data and measuring the progress with the implementation of innovative solutions.

An important purpose of the forum is to advance the dialogue between industry, regulatory agencies, and academia around policy, regulation, development, and review of medical products in the context of today's scientific and regulatory environments. The program is developed collaboratively by FDA, industry, and academic experts who team up to ensure that each session brings all stakeholder perspectives to the discussion.

Meeting Designed For

- Access & Value
- Clinical Development & Operations
- Clinical Safety & Pharmacovigilance
- Data & Data Standards
- Preclinical & Early Phase Research
- Regulatory
- Quality Assurance / Control & CMC
- Statistics

Schedule At-A-Glance

SHORT COURSE | TUESDAY, MARCH 16

10:00AM-2:00PM	**Short Course**: Estimand Framework Implementation

SHORT COURSE | TUESDAY MARCH 21

10:00AM-2:00PM	**Short Course:** Methods to Support Patient-Focused Medical Product Development: Key Concepts from FDA's Patient-Focused Drug Development Guidance Series

SHORT COURSE | THURSDAY MARCH 23

10:00AM-2:00PM	**Short Course:** Group Sequential and Adaptive Designs in Drug Development: Methodology, Practical Aspects, and Examples

DAY ONE | WEDNESDAY, MARCH 29

10:00-10:15AM	**Welcome and Opening Remarks**
10:15-11:00AM	**Keynote:** The Future of Evidence Generation: Planning for Novel Data Modalities  **Amy Abernethy, MD, PhD**, President of Clinical Studies Platforms Alphabet's Verily
11:00-11:15AM	**Break**
11:15AM-12:30PM	**Session 1:** The Critical Role of Covariates in Clinical Trial Design and Analysis
12:30-1:00PM	**Break**
1:30-2:45PM	**Session 2:** Complex Innovative Trials Designs: Current Perspectives and Future Directions
2:45-3:00PM	**Break**
3:00-4:15PM	**Session 3:** Recent updates on FDA User Fee Amendments

DAY TWO | THURSDAY, MARCH 30

10:00-11:15AM	**Session 4:** Novel Approaches for the Clinical Development of Biosimilars
11:15-11:30AM	**Break**
11:30AM-12:45PM	**Session 5:** Information and Case Studies Related to ICH E11A draft guidance on Pediatric Extrapolation
12:45-1:00PM	**Break**
1:00-2:15PM	**Session 6:** Advanced Statistical Methods to Borrow External Information
2:15-2:30PM	**Break**
2:30-3:45PM	**Session 7:** Innovation for Dose Optimization - Updates from Project Optimus

DAY THREE | FRIDAY, MARCH 31

10:00-11:15AM	**Session 8:** Machine Learning and Safety Statistics
11:15-11:30AM	**Break**
11:30AM-12:45PM	**Session 9:** Design Considerations in Using RWE/RWD in Clinical Trials
12:45-1:15PM	**Break**
1:15-2:45PM	**Session 10:** The Estimand Framework in the Context of Benefit-Risk Assessments
2:45-3:00PM	**Closing Remarks**

Learning Objectives

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

- Discuss approaches to collecting novel types of data for evidence generation and analytic methods needed to power new approaches to data
- Identify and discuss issues relevant to applying the ICH E9(R1) framework to complex innovative trials
- Identify key updates for each user fee program, including launching the Rare Disease Endpoint Advancement (RDEA) Pilot program under PDUFA VII
- Recognize the purpose of the Comparative Clinical Endpoint Studies in Biosimilar Development Program and apply Bayesian designs for biosimilar product development
- Summarize and apply principles of ICH E11A draft guidance to pediatric drug development
- Discuss updates in FDA's Project Optimus and ongoing development of dose optimization guidance and recognize approaches to develop a composite endpoint to select an optimal dose
- Describe the current use of ML in analysis of safety data by the pharmaceutical industry and regulatory agencies and identify areas of potential future applications and methods development
- Explain strengths of the estimand framework for jointly assessing efficacy and safety of a treatment and identify challenges in joint assessment of efficacy and safety
- Describe the general ideas of various methods to borrow information from external data and discuss potential applications in regulatory clinical trials
- Recognize statistical methods leveraged in the analysis of RWD and describe innovative approaches of combining RWD and clinical trial data in decision making

Continuing Education Credits

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- March 16, 2023 – Short Course 1: Estimand Framework Implementation: IACET .4 CEUs
- March 21, 2023 – Short Course 2: Methods to Support Patient-Focused Medical Product Development: Key Concepts from FDA's Patient-Focused Drug Development Guidance Series: IACET .4 CEUs
- March 23, 2023 – Short Course 3: Group Sequential and Adaptive Designs in Drug Development: Methodology, Practical Aspects, and Examples: IACET .4 CEUs
- March 29 - 31, 2023 – DIA/FDA Biostatistics Industry and Regulator Forum: No CEUs

***IACET CEUs are only available for the Short Course(s). Participants must attend the entire virtual short course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.**

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Disclosure statements are included with each speaker's biographical sketch.

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