DIA

DIA/FDA Biostatistics Industry and Regulator Forum

Virtual Event: April 6-8

PROGRAM CO-CHAIRS

Brenda Crowe, PhD
Senior Research Advisor, Global Statistical Sciences
Eli Lilly and Company

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Mathematical Statistician
CDER, FDA

PROGRAM COMMITTEE

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Vice President, Data Science and Statistician
Medidata, a Dassault Systèmes Company

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Senior Director, Statistical Research and Innovation
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Yueqin Zhao, PhD
Lead Mathematical Statistician, OB, OTS, CDER, FDA

PROGRAM ADVISORS

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

Overview

The *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, combination, and other medical products. As an open forum to discuss timely topics of mutual theoretical and practical interest to statisticians and clinical trialists, 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.

Who Should Attend

Professionals from industry, academia, and government involved in all phases of the medical product lifecycle who are interested in the application of statistics to advance biopharmaceutical development and accessibility including:

- Biotechnology
- Clinical Data Management/ eClinical
- Comparative Effectiveness/ Health Technology Assessment
- Clinical Safety/ Pharmacovigilance
- Clinical Research
- eClinical
- Pharmacology
- Quality Assurance, Control
- Regulatory Affairs
- Research & Development
- Study Endpoints/Clinical Outcomes Assessments
- Statistics

Highlights

What is happening at *DIA/FDA Biostatistics Industry and Regulator Forum*:

- In-depth discussions on new, revised, and anticipated guidances and emerging policy issues
- Senior Leaders Town Hall: An open discussion lead by an expert panel of leaders from industry and regulatory agencies
- Each session is co-chaired by an Industry-FDA team
- DIA Statistics and Data Science Open Community Meeting: Yes, You Can Use R in Regulatory Submissions
- Two Short Courses: Design, Analysis and Evaluation of Confounding Bias Using RWD and Practical Bayesian Approaches in Healthcare: Industry and Regulatory Perspectives

Schedule At-A-Glance

SHORT COURSE | TUESDAY, MARCH 29

10:00AM-2:00PM	**Short Course:** Design, Analysis and Evaluation of Confounding Bias Using RWD

SHORT COURSE | FRIDAY, APRIL 1

10:00AM-2:00PM	**Short Course:** Practical Bayesian Approaches in Healthcare: Industry and Regulatory Perspectives

DAY ONE | WEDNESDAY, APRIL 6

10:00-10:45AM	**Welcome and Opening Remarks and Keynote:** Estimating Per-protocol Effects: Randomized Trials Analyzed like Observational Studies
10:45-11:00AM	Break
11:00AM-12:30PM	**Session 1:** Advancing Decentralized Clinical Trials in Drug Development: Challenges, Opportunities, and Future Directions
12:30-1:30PM	Break
1:30-3:00PM	**Session 2:** Synthetic Controls and Causal Inference
3:00-3:15PM	Break
3:15-4:45PM	**Session 3:** Dose Optimization in Oncology: Finding the "Right" Dose for Patients

DAY TWO | THURSDAY, APRIL 7

10:00-11:30AM	**Session 4:** Challenges in COVID-19 Vaccine Development for Adults and Pediatrics: A Journey from Clinical Trials to Real-World
11:30-11:45AM	Break
11:45AM-1:15PM	**Session 5:** Artificial Intelligence (AI) and Machine Learning (ML) in Drug Development
1:15-2:15PM	Break
2:15-3:15PM	**Session 6:** DIA Data Science and Statistics Community Meeting Discussion: Yes, You Can Use R in Regulatory Submissions
3:15-3:30PM	Break
3:30-4:45PM	**Session 7:** Complex Innovative Design Pilot Program

DAY THREE | FRIDAY, APRIL 8

10:00-11:30AM	**Session 8:** Digital Health in Clinical Development
11:30-11:45PM	Break
11:45-1:15PM	**Session 9:** Understanding Logistical and Regulatory Barriers to Using Real-World Data in New Drug Applications or Supplements
1:15-1:45PM	Break
1:45-3:15PM	**Session 10:** Statistical Leaders Town Hall
3:30-4:00PM	**Plenary Session Featuring Dr. Robert Califf**
4:00-4:15PM	**Closing Remarks**

Learning Objectives:

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

- Discuss the use of RWD and methods used to minimize bias and confounding variables
- Discuss utilizing Bayesian methods to support decision making in drug development and clinical trial design and analysis
- Describe how the ICH E9(R1) esteemed framework can be used to clarify the impact of decentralized clinical trials on the scientific question(s)
- Identify statistical issues, safety, and efficacy measures in the design of pediatric Covid-19 vaccine trials and potential statistical solutions to the uncertainty of developing vaccines
- Evaluate the uses of synthetic controls in the regulatory and nonregulatory spaces

SHORT COURSE | TUESDAY, MARCH 29

10:00AM-2:00PM

Short Course: Design, Analysis and Evaluation of Confounding Bias Using RWD

Short Courses require an additional registration fee. You do not need to be registered for the forum to attend

Short Course Chairs
Yuan-Li Shen, DrPH, Deputy Division Director, Division of Biometrics V, OB, OTS, CDER FDA

Yueqin Zhao, Staff Fellow, OB, OTS, CDER, FDA

Real-world evidence (RWE) and Real-world data (RWD) are playing an increasing role in health care decisions, especially since the passage of the 21st Century Cure Act in 2016. Due to the increasing use of RWD in the regulatory setting, statisticians have encountered greater challenges in trial design and data interpretation. Some of the issues concerning RWD include understanding data sources, determining data relevancy, consideration of measurement errors, variable balancing techniques, and evaluating confounding bias. Many of these issues may not be routinely encountered with randomized trials, and they are more often handled by the Epidemiology Department. Due to the rising role of RWD in health care, it is important to become familiar with analyzing these data to generate an appropriate and efficient use of RWD and provide constructive advice to clinicians. In this session, Professor Michele Funk, the primary investigator of the DETECTe (Detailing and Evaluating Tools to Expose Confounded Treatment Effects) Demonstration Project, will provide information on data sources, research bias and confounding, and various statistical methods used with RWD.

At the conclusion of this session, participants should be able to

- Identify the pros and cons of different RWD data sources
- Recognize the different methods used with RWD to minimize bias and evaluate confounding variables
- Define practical examples using RWD
- Recognize the applications and software used in RWD
- Interpret RWD results and recognize their limitations

Learning From our Epidemiology Colleague: Design, Analysis and Evaluation of Confounding Using RWD
Michele Funk-Jonsson, **PhD**, Associate Professor of Epidemiology, Director of the Center for Pharmacoepidemiology, University of North Carolina at Chapel Hill.

10:00AM-2:00PM

Short Course: Practical Bayesian Approaches in Healthcare: Industry and Regulatory Perspectives

Short Courses require an additional registration fee. You do not need to be registered for the forum to attend

Short Course Chairs

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

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

In recent years, Bayesian methods have generated extensive discussion in clinical trials. A Bayesian approach provides the formal framework to incorporate external information into the statistical analysis of a clinical trial. It helps to strategically borrow information across different, potentially heterogeneous, groups such as between adults and pediatrics, disease subgroups, regions, etc. This is particularly useful in planning and executing successful global clinical trials. The course will cover some modern applications of Bayesian methods in healthcare with an emphasis on practical and regulatory aspects. Along with methods, the course will demonstrate applications in real-life clinical trials and discuss the impact of utilizing these approaches in decision-making.

This course is beneficial for statistical researchers working in the pharmaceutical industry, academic institutions, or regulatory agencies, or statistics students. The course is oriented toward practitioners who are interested in (i) using Bayesian methods in medical product development; (ii) understanding the regulatory perspectives; and (iii) learning effective ways to communicate with nonstatistical stakeholders.

At the conclusion of this session, participants should be able to

- Discuss utilizing Bayesian methods to support decision making in drug development and clinical trial design and analysis
- Use available open-source software's for implementing Bayesian methods in real-life clinical trial
- Explain the benefits and risks of Bayesian approaches
- Understand the regulatory landscape while using Bayesian methods in medical product development
- Assess the findings of Bayesian analyses and communicate these findings with non-statisticians

Instructors

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

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

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

Mark Rothmann, PhD, Director, Division of Biometrics II, (CDER), FDA

James Travis, PhD, Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, CBER, FDA

10:00-10:45AM

Welcome and Opening Remarks and Keynote: Estimating Per-protocol Effects: Randomized Trials Analyzed like Observational Studies

Session Chairs

Brenda Crowe, PhD, Senior Research Advisor, Global Statistical Sciences, Eli Lilly and Company

Fairouz Makhlouf, PhD, Mathematical Statistician, CDER, FDA

The causal estimand of interest in many randomized trials is the intention-to-treat effect, that is, the effect of being assigned to the treatment strategies of interest. However, in many randomized trials, patients and doctors are more interested in another causal estimand: the per-protocol effect, that is, the effect of following the assigned treatment strategies as indicated in the protocol during the follow-up period. Valid estimation of the per-protocol effect generally requires adjustment for pre- and post-randomization prognostic factors associated with adherence and loss to follow-up. This talk describes the relative advantages and disadvantages of intention-to-treat and per-protocol effects, and reviews several case studies in cardiovascular disease, infectious disease, and cancer.

Keynote Speaker

Miguel Hernan, DrPH, MD, Professor, Department of Epidemiology, Harvard T.H. Chan School of Public Health

Speaker

Representative Invited, FDA, United States

10:45-11:00AM Break

11:00AM-12:30PM

Session 1: Advancing Decentralized Clinical Trials in Drug Development: Challenges, Opportunities, and Future Directions

Session Chairs

Yuan-Li Shen, DrPH, Deputy Division Director, Division of Biometrics V, OB, OTS, CDER, FDA

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

Due to the COVID-19 pandemic, the need to have more flexible approaches for conducting clinical trials became essential. Decentralizing elements of a clinical trial enable information to be generated and captured without traditional clinical trial infrastructures. As an example, endpoints can be captured remotely using digital technologies. By reducing the burden of trial participation on patients and their caregivers, decentralization is likely to facilitate the recruitment, retention, and engagement of a more diverse patient population. However, decentralizing elements of a trial may impact the scientific question(s) the study can answer. Additionally, increased heterogeneity amongst remotely collected data influences sample size requirements and analysis strategies. In this session, through discussion and case studies, we will: i) explore how the ICH E9(R1) estimand framework can evaluate the impact of decentralization on study objectives; ii) discuss statistical challenges with regards to establishing endpoint validity and reliability; and iii) highlight opportunities for leveraging innovative analytical approaches.

Speaker

Rima Izem, PhD, Associate Director Statistical Methodology, Novartis, Switzerland

Kannan Natarajan, PhD, Senior Vice President, Head of Global Biometrics and Data Management, Pfizer, Inc.

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

12:30-1:30PM Break

1:30-3:00PM

Session 2: Synthetic Controls and Causal Inference

Session Chairs
Hana Lee, PhD, Senior Statistical Reviewer, OB, OTS, CDER, FDA

Ruthie Davi, PhD, MS, Vice President, Data Science and Statistician, Medidata, a Dassault Systèmes Company

This session will explore the use of propensity scores or other balancing algorithms to create synthetic or external controls to aid in medical product development. Examples include

- Alignment of a synthetic control to a single arm trial early in development to facilitate go/no-go decisions
- Utilizing a synthetic control arm for enhanced understanding of a treatment effect observed in a single arm trial to support an accelerate approval submission

The main advantage of the synthetic control, over traditional benchmarks referencing medical literature or created with clinical intuition, is the potential for well-balanced condition of the synthetic control patients and the investigational patients at baseline. This session will discuss general principles with a focus on examples. We will discuss cases where synthetic controls have been used, the statistical methods applied, and the implications of doing so. Examples may include regulatory or nonregulatory applications.

Real-world Evidence to Support Regulatory Decision-making for Medicines: Considerations for External Control Arms
Mehmet Burcu, PhD, MS, Senior Principal Scientist, Epidemiology, Merck & Co, Inc.

Use of a Synthetic Control Arm in Medical Product Development
Xiang Yin, PhD, Vice President, Data Science, Acorn AI By Medidata, A Dassault Systèmes Company

Regulatory Review Experience of Single-Arm Studies Utilizing External Trial Information
Yeh-Fong Chen, PhD, Mathematical Statistician (Team Lead), Office of Translational Sciences, CDER, FDA

3:00-3:15PM Break

3:15-4:45PM

Session 3: Dose Optimization in Oncology: Finding the "Right" Dose for Patients

Session Chairs
Mallorie Fiero, PhD, Lead Mathematical Statistician, CDER, FDA

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

Drug development in oncology presents several challenges unique to this therapeutic area. Balancing the benefits and risks provides longer survival while maintaining or improving the quality of life. In the current oncology paradigm, the objective of phase 1 trials is to determine the highest tolerable dose, based on the assumption that higher doses will provide greater efficacy. Without formal dose-finding, the current paradigm does not adequately evaluate inter-patient variability in treatment response and toxicity. Moreover, it provides a limited picture of long-term toxicity. This session will focus on different strategies of dose determination for oncology drugs that seek to optimize dose selection as well as enable a complete understanding of the relationship between drug exposure and clinical outcomes.

Dose Optimization in Oncology Trials
Joyce Cheng, PhD, Lead Mathematical Statistician, FDA

Speakers
Paul Frewer, **MSc Statistics**, Senior Director, Early Oncology Statistics, Oncology Biometrics, AstraZeneca, United Kingdom

Chris Boshoff MD, PhD, FMedSci, Chief Development Officer – Oncology, Pfizer, Inc.

Cara Rabik, MD, PhD, Medical Officer, FDA

Stacy Shord, PharmD, Deputy Division Director, FDA

10:00-11:30AM

Session 4: Challenges in COVID-19 Vaccine Development for Adults and Pediatrics: A Journey from Clinical Trials to Real-World

Session Chairs
Shiowjen Lee, PhD, Deputy Director, Division of Biostatistics, OBPV, CBER, FDA

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

Vaccine development is a lengthy and expensive process. It typically takes multiple candidates and many years to produce a licensed vaccine. Conducting vaccine efficacy trials during an outbreak such as the COVID-19 pandemic poses unique challenges. It will generate simultaneous demand for vaccines around the world. Therefore, a strategic rollout plan for vaccines is required. An accelerated development plan requires innovations from all aspects of research and development including strategic design of clinical trials, defining clinical endpoints, and analyzing the study data. In addition, the development plan for the pediatric population will require additional safety considerations including the choice of appropriate dosing. This session will discuss the approval of vaccines and highlights issues with Covid-19 clinical development and rollout. It will compare the different issues with adult and pediatric development plans. Speakers will discuss the statistical challenges and solutions for the vaccine development and rollout plan.

Speakers
John Scott, PhD, MA, Director, Division of Biostatistics, OBE, CBER, FDA

Kennethy Koury, PhD, Vice President, Head of Vaccine Clinical Research Biostatistics, Pfizer, Inc.

Dean Follmann, PhD, Assistant Director for Biostatistics; NIAID Chief Biostatistics Research Branch, National Institute of Allergy and Infectious Diseases

11:30-11:45AM Break

11:45AM-1:15PM

Session 5: Artificial Intelligence (AI) and Machine Learning (ML) in Drug Development

Session Chairs
Pabak Mukhopadhyay, PhD, Executive Director, Late Statistics, Head of Breast Cancer Strategy, AstraZeneca

Paul Schuette, PhD, MA, Mathematical Statistician, Scientific Computing Coordinator, FDA

Artificial intelligence and machine learning (AI/ML) have the potential to complement current processes and procedures as well as revolutionize drug discovery and patient selection. In this session, we will highlight key learnings, caveats, and issues as well as areas to consider through case study exploration. Examples shared will include early discovery and patient selection. The session will demonstrate the present utility and future potential of AI/ML for regulatory science and will discuss the challenges and considerations when using AI/ML methods with RWD in regulatory decision making.

Learnings from Developing an ML Prognostic Model of Early Risk of Mortality for Treatment of Patients with Immune Checkpoint Inhibitors (ICIs)
Jolyon Faria, PhD, MSc, Data Science Director, AstraZeneca, United Kingdom

Machine Learning Considerations In Causal Inference Using Real-World Data
Di Zhang, PhD, Statistical Reviewer, OB, OTS, CDER, FDA

Turbocharging Drug Discovery with Machine Learning - An Application
Gregory Steeno, PhD, MS, Senior Director, Research Statistics, Pfizer

1:15-2:15PM Break

2:15-3:15PM

Session 6: DIA Data Science and Statistics Community Meeting Discussion: Yes, You Can Use R in Regulatory Submissions

Session Chairs
Elena Rantou, PhD, Lead Mathematical Statistician, FDA

Brenda Crowe, PhD, Senior Research Advisor, Global Statistical Sciences, Eli Lilly and Company

This session will highlight how R programming language is used in the process of submitting drug applications to the FDA from industry perspective along with the process of regulating and approving drugs at the FDA. A panel discussion with a question-and-answer format will follow.

Achieving Regulatory Approval Using R
Tae Hyun (Ryan) Jung, PhD, Senior Statistical Reviewer, FDA

Yes, You Can use R in Regulatory Submissions
Coline Zeballos, MSc, R Strategy Lead, Roche, Switzerland

Panelist
Ning Leng, PhD, People and Product Lead, Genentech, Inc.

3:15-3:30PM Break

3:30-4:45PM

Session 7: Complex Innovative Design Pilot Program

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

Fairouz Makhlouf, PhD, Mathematical Statisticain, CDER, FDA

To promote innovation and efficiency, FDA started Complex Innovative Design (CID) Pilot Program in 2018. Over the years, five use cases proposed by different sponsors were accepted by FDA and significant progress had since been made. In this session, FDA speakers and sponsors will give the audience an update on the progress and share the challenges and lessons learned from CID pilot program.

Moving Forward: The CID Pilot Program
Representative Invite, FDA

Label-enabling Dynamic Borrowing with External Control for OS - FDA Complex Innovative Designs Pilot Program
Jiawen Zhu, PhD, Senior Principal Statistical Scientist, Genentech, a Member of the Roche Group

FDA Commentary on CID Case Study in SLE
Cesar Torres, PhD, Mathematical Statistician, CDER, FDA

FDA Commentary on DLBCL External Control Design in CID Program
Jonathon Vallejo, PhD, Lead Mathematical Statistician, CDER, FDA

CID Case Study in SLE: Experiences and Considerations
May Mo, MBA, MS, Executive Director, Design and Innovation, Amgen

DAY THREE | FRIDAY, APRIL 8

10:00-11:30AM

Session 8: Digital Health in Clinical Development

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

Andrew Potter, PhD, Mathematical Statistician, OB, OTS, CDER, FDA

With the advancement of digital health technologies, cloud computing power, and big data analytics, there is an opportunity to develop an integrated strategy to optimize clinical trial designs and advance the development of innovative medicines. In this session, we will learn from the industry and FDA speakers how digital technologies are leveraged to support clinical development.

Digital Health from Clinical Trials to Clinical Practice
Alex Morozov, MD, PhD, Vice President, Head of Digital Health - Global Drug Development, Bristol Myers Squibb

Application of Digital Medicine in Drug Development
Sandeep Menon, MD, PhD, Chief Scientific Officer of Artificial Intelligence and Digital Science and Senior Vice President, Pfizer, Inc

Remote Data Acquisition in Clinical Investigations Using Digital Health Technologies
Christina Webber, General Engineer FDA

11:30-11:45PM Break

11:45-1:15PM

Session 9: Understanding Logistical and Regulatory Barriers to Using Real-World Data in New Drug Applications or Supplements

Session Chair
Yueqin Zhao, **PhD**, Lead Mathematical Statistician, OB, OTS, CDER, FDA

Judith Maro, PhD, MS, Assistant Professor, Department of Population Medicine, Harvard Medical School and the Harvard Pilgrim Health Care Institute

This session is designed to introduce biostatisticians to some of the regulatory concerns when using Real-World Data to support New Drug Applications or Supplemental New Drug Applications. Prior use cases include real world data as external control arms primarily in cancer and rare disease therapeutic areas. Real-World Data holds many promises to enhance data from what would otherwise be single arm trials, however use of data not owned by the sponsor brings logistical and statistical challenges for incorporation. Data granularity and access can be significantly different from data gathered explicitly to support the trial.

Real-World Evidence Data Landscape
Mary Beth Ritchey, PhD, FISPE, Principal and Owner, Med Tech Epi, LLC

Regulatory Considerations for Access to Real-World Data
Stefanie Kraus, JD, MPH, Senior Regulatory Counsel, FDA

Presentation of Use Case and Statistical Considerations
Sajan Khosla, PhD, Executive Director, Head of Real-World Evidence, Oncology R&D, Astra Zeneca

1:15-1:45PM Break

1:45-3:15PM

Session 10: Statistical Leaders Town Hall

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

Lisa Lupinacci, PhD, MS, Senior Vice President, Biostatistics and Research Decision Sciences, Merck and Co., Inc.

This will be a panel that discusses topics and/or tells personal stories that highlight professional development issues for statisticians, every day skills needed by statisticians, and/or approaches to handling professional or statistical challenges. Tentative: The audience will gain perspectives from senior statistics leaders about skills needed to navigate the complex world of drug/vaccine development and tips for focusing on what is most impactful, including navigation of the remote work environment.

Speakers
Xun Chen, PhD, Global Head of Biostatistics and Programming, Sanofi

Sylva Collin, PhD, Director, Office of Biostatistics, FDA

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

Lisa Lupinacci, PhD, MS, Senior Vice President, Biostatistics and Research Decision Sciences, Merck and Co., Inc.

Chris Miller, MS, Vice President, Biometrics, Late-Stage Development, Respiratory and Immunology, AstraZeneca

John Scott, PhD, MA, Director, Division of Biostatistics, Office of Biostatistics and Epidemiology, CBER, FDA

Lilly Yue, PhD, Acting Division Director, Biostatistics, FDA

3:30-4:00PM

Plenary Session featuring Dr. Robert Califf

Session Chairs
Brenda Crowe, PhD, Senior Research Advisor, Global Statistical Sciences, Eli Lilly, and Company

Fairouz Makhlouf, PhD, Mathematical Statistician, CDER, FDA

Speaker
Robert Califf, MD, Commissioner, FDA

4:00-4:15PM

Closing Remarks

Session Chairs
Brenda Crowe, PhD, Senior Research Advisor, Global Statistical Sciences, Eli Lilly, and Company

Fairouz Makhlouf, PhD, Mathematical Statistician, CDER, FDA