Virtual

Apr 28, 2025 9:00 AM - Apr 28, 2025 4:00 PM

(US Eastern Standard Time)

Clinical Innovation and Biostatistics Summit

Gain access to novel, thought-provoking findings and collaborate with experts on charting the best path forward in biostatistics and clinical trial innovation.

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Print Agenda

Day 1 Apr 28, 2025

9:00 AM — 10:35 AM

Opening Remarks and Session 1: Regulatory Updates and Experiences

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Track: General Session

Session Chair(s)

Maria Vassileva, PhD

Chief Science and Regulatory Officer
DIA, United States

Dr. Vassileva has decades of experience with managing complex multi-stakeholder biomedical research programs. She spent most of her career in the nonprofit sector, leading the Science Team at the Arthritis Foundation, and working at the Foundation for NIH and the American Association for the Advancement of Science. She was also on the leadership teams of two health research organizations, serving as project director on multiple government contracts. Her areas of expertise include musculoskeletal, metabolic, immunity and inflammation disorders, as well as patient engagement. She received her PhD in Biochemistry and Cell Biology from Johns Hopkins.

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

Satrajit Roychoudhury, PhD

Executive Director, Statistical Research and Innovation
Pfizer, Inc., United States

Dr. Satrajit Roychoudhury is an Executive Director and the head of Statistical Research and Innovation group in Pfizer Inc. Prior to joining, he was a member of Statistical Methodology and Consulting group at Novartis. His primary expertise includes implementation of innovative statistical methodology in clinical trials. He has co-authored several publications/book chapters in this area and provided statistical training at major conferences. His areas of research include the use of survival analysis, model-informed drug development and Bayesian methods in clinical trials.

Yun Wang, PhD

Deputy Division Director, OTS, CDER
FDA, United States

Dr. Yun Wang is the Deputy Division Director for Division of Biometrics II in the Office of Biostatistics at CDER/FDA since March 2021. Before taking her current role, Dr. Wang was a statistical team leader and reviewer supporting anti-diabetic and hematologic products development in OB/FDA from 2011 – 2021. Prior to joining FDA, Dr. Wang was a senior principal biostatistician at Novartis Oncology from 2008-2011, and an assistant professor in the University of Pittsburgh from 2005 – 2008.

Speaker(s)

The Mission of the New Initiative on Clinical Trial Innovation (C3TI) at FDA

ShaAvhree Y. Buckman-Garner, MD, PhD

Director, Office of Translational Sciences, CDER
FDA, United States

ShaAvhrée Buckman-Garner, MD, PhD, FAAP is the Director of the Office of Translational Sciences, Center for Drug Evaluation and Research (CDER), at the FDA. Prior to serving as Director of OTS, Dr. Buckman-Garner served as Deputy Director for OTS and as medical team leader in the Division of Pediatric Drug Development, Office of Counter Terrorism and Pediatric Drug Development, CDER. Dr. Buckman-Garner received her MD and PhD degrees with an emphasis on molecular cell biology from Washington University School of Medicine. She completed Pediatric specialty training at Baylor College of Medicine.

Regulatory Updates on Several Statistical Topics

Gregory Levin, PhD

Associate Director for Statistical Science and Policy, OB, OTS, CDER
FDA, United States

Gregory Levin is the Associate Director for Statistical Science and Policy in the Office of Biostatistics in the FDA's Center for Drug Evaluation and Research. He received a Ph.D. in biostatistics from the University of Washington in 2012. Greg has experience supporting drug review across a wide range of therapeutic areas and has represented CDER on several policy and guidance working groups, including efforts related to adaptive design, master protocols, benefit-risk, and the evaluation of effectiveness.

Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Current Science and Considerations in 2025

Sarah Yim, MD

Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER
FDA, United States

Sarah Yim, M.D. has been the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND), FDA since 2019. Prior to that, she spent 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology drug review in OND. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences, and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.

10:35 AM — 10:45 AM

Break (on your own)

10:45 AM — 12:30 PM

Session 2: Clinical Trial Innovative Designs and Approaches – Setting the Context and Presenting the Industry Perspectives

Innovation in clinical trials is an ongoing goal with a desired outcome of improving efficiency when investigating new therapies while maintaining the necessary scientific rigor for acceptance in clinical use as well as regulatory approval. Three general areas of innovation are the use of Master Protocols, seamless trial designs, and trials borrowing information from external sources. This session will include one session discussing the use of Master Protocols to obtain trial efficiency, a second session discussing recent design innovations to facilitate efficient learning through seamless phase 2/3 and enrichment designs and the third will discuss the strategy of borrowing information while also presenting design considerations such relevance/comparability of external information and appropriate statistical methods. The session will conclude with audience questions and discussion.

Learning Objective :

- Identify the need for improvements in innovation in trial design and conduct
- Summarize in what manner Master Protocols improve efficiency in trial conduct
- Recognize the potential for efficient learning through use of seamless phase 2/3 or enrichment designs
- Evaluate the appropriate use of borrowed information and necessary statistical methods

Track: General Session

Session Chair(s)

Michelle A Detry, PhD

Director, Adaptive Trial Execution & Senior Statistical Scientist
Berry Consultants, LLC, United States

Michelle Detry, PhD, is the Director of Adaptive Trial Execution and a Senior Statistical Scientist for Berry Consultants. Dr. Detry's expertise is in the implementation of adaptive clinical trials, including platform trials. As part of her role in implementing Berry Consultant's trial designs she is a member of numerous statistical analysis committees that conduct the interim analyses. In addition, she has expertise in clinical trial design, reporting for Data Monitoring Committees, and also serves on Data Monitoring Committees.

Speaker(s)

Master Protocols

Elyse Katz, PhD

Senior Product Management Support, Warfighter Brain Health PMO, USAMMDA
Tunnell Government Services, Inc., United States

Elyse Katz, PhD, supports the US Department of Defense's efforts to increase the medical readiness of active-duty service members through the development and deployment of psychological health and traumatic brain injury diagnostics and therapeutics. To facilitate this work, she leverages her background in biomarker and clinical development in Neuroscience, as well as experience working collaboratively with colleagues from other government agencies, academic institutions, and industry partners.

Recent Design Innovation

Scott Berry, PhD

President and Senior Statistical Scientist
Berry Consultants LLC, United States

Scott Berry is President and a Senior Statistical Scientist at Berry Consultants, LLC. He earned his MS and PhD in statistics from Carnegie Mellon University and was an Assistant Professor at Texas A&M University before co-founding Berry Consultants in 2000. His primary interests are in Bayesian Analysis, Design of Innovative Trials, Platform Trials, Clinical Trial Simulation, and Hierarchical Modeling.

Challenges and Opportunities for Borrowing External Data

Satrajit Roychoudhury, PhD

Executive Director, Statistical Research and Innovation
Pfizer, Inc., United States

Dr. Satrajit Roychoudhury is an Executive Director and the head of Statistical Research and Innovation group in Pfizer Inc. Prior to joining, he was a member of Statistical Methodology and Consulting group at Novartis. His primary expertise includes implementation of innovative statistical methodology in clinical trials. He has co-authored several publications/book chapters in this area and provided statistical training at major conferences. His areas of research include the use of survival analysis, model-informed drug development and Bayesian methods in clinical trials.

Challenges and Opportunities for Borrowing External Data

Yun Wang, PhD

Deputy Division Director, OTS, CDER
FDA, United States

Dr. Yun Wang is the Deputy Division Director for Division of Biometrics II in the Office of Biostatistics at CDER/FDA since March 2021. Before taking her current role, Dr. Wang was a statistical team leader and reviewer supporting anti-diabetic and hematologic products development in OB/FDA from 2011 – 2021. Prior to joining FDA, Dr. Wang was a

senior principal biostatistician at Novartis Oncology from 2008-2011, and an assistant professor in the University of Pittsburgh from 2005 – 2008.

12:30 PM — 1:00 PM

Lunch Break (on your own)

1:00 PM — 2:00 PM

Session 3: Case Study 1: Master Protocol Implementation in Oncology

This next two sessions will showcase two compelling case studies highlighting innovative approaches to clinical trial design and execution. Each case study provides a deep dive into real-world applications, focusing on the challenges, solutions, and outcomes of cutting-edge methodologies in diverse therapeutic areas.

Case Study 1 will discuss Master protocol in oncology. A practical example of effective master protocol design and execution will be presented. Regulatory opinions on implementation and evaluation will also be discussed.

Learning Objective :

- Understand the principles and benefits of master protocol designs and how they are applied in oncology trials
- Identify innovative trial design strategies in neuroscience
- Apply key learnings from these case studies to inform the design and execution of future clinical trials in your own therapeutic areas

Track: General Session

Session Chair(s)

Lisa Rodriguez, PhD

Deputy Division Director, OB, OTS, CDER
FDA, United States

Dr. Rodriguez is the Deputy Division Director of the Division of Biometrics IX at CDER/FDA. She earned her PhD from Cornell University and certificate in Strategic Decision and Risk Management from Stanford University. Prior to joining FDA in 2012, Dr. Rodriguez supported a variety of therapeutic areas in industry. Her work at FDA has covered issues in oncology, hematology, meta-analyses, evaluation of biomarker and PRO/COA endpoints, survival analyses, and adaptive designs, and she recently served as co-organizer of the FDA-AACR-ASA Workshop on Overall Survival. She co-leads the Benefit-Risk Assessment Planning (BRAP) Taskforce within the ASA Biopharm Safety Working Group and is part of several internal FDA scientific working groups.

Speaker(s)

Speaker

Timothy Cloughesy, MD

Professor of Neurology, Director, UCLA Brain Tumor Center
UCLA, United States

Dr. Timothy Cloughesy is a distinguished professor at UCLA and founding director of its neuro-oncology program. He is global principal investigator of GBM AGILE, an adaptive platform trial for glioblastoma, and co-founder, board member, and CMO of the Global Coalition for Adaptive Research, which sponsors GBM AGILE and other innovative platform trials. His work focuses on novel trial design, biomarker integration, and translational research in brain cancer. He played key roles in the development of bevacizumab and vorasidenib, and is a co-inventor of the EGFR inhibitor ERAS-801. He has authored over 450 papers and is a member of the Association of American Physicians.

Xiaoxue Li, PhD

Lead Mathematical Statistician
FDA, United States

Dr. Li is a statistical Team Lead in FDA, Center for Drug Evaluation and Research (CDER), Office of Biometrics V, supporting the review of oncology drug products. She has nearly 7 years of experience working in FDA. She received her Ph.D. in Biostatistics from University of Pittsburgh and worked at Dana-Farber Cancer Institute for three and half years before she joined FDA.

2:00 PM — 2:30 PM

Session 3: Case Study 2: A Case Study of a Hybrid Control Design in Diffuse B-Cell Lymphoma

The Complex Innovative Trial Design (CID) Pilot Meeting Program was initiated by FDA in 2018 to support the goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. Since then, the FDA published five examples including the case by Roche/Genentech completed in 2021. In the presentation, we will introduce the FDA CID pilot program, share our proposed study design, key discussions during the pilot program and learnings. Our proposed ph3 study design involves utilizing both internal and external control data to support the analysis of secondary endpoint overall survival in DLBCL.

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

- Introduce the FDA CID Pilot Program
- Describe our proposed study design
- Share key discussions during the pilot program and learnings

Track: General Session

Session Chair(s)

Satrajit Roychoudhury, PhD

Executive Director, Statistical Research and Innovation
Pfizer, Inc., United States

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Speaker(s)

Speaker

Herbert Pang, PhD, MBA

Expert Statistical Scientist
Genentech, A Member of the Roche Group, United States

Herbert (Herb) Pang is an Expert Statistical Scientist at Genentech/Roche. His research interests include real-world evidence for drug development, machine learning, biomarker discovery, -omics data, and the design and analysis of clinical trials. Herb obtained his PhD in Biostatistics from Yale University in 2008 and BA in Mathematics and Computer Science from the University of Oxford in 2002. He was formerly a tenured Associate Professor at the University of Hong Kong where he led a team to do research in biostatistics and bioinformatics. He remains as an adjunct faculty in the Department of Biostatistics and Bioinformatics at Duke University School of Medicine.

2:30 PM — 2:45 PM

Break (on your own)

2:45 PM — 3:45 PM

Session 4: Challenges and Opportunities for Implementing Innovative Designs Including Master Protocols and Borrowing External Data

Join academic, industry and regulatory experts for an interactive discussion on the challenges and opportunities of master protocols, innovative clinical designs and approaches, including borrowing external data. Audience participants can enter their questions to be answered during the discussion.

Session Chair(s)

Lisa Rodriguez, PhD

Deputy Division Director, OB, OTS, CDER
FDA, United States

Dr. Rodriguez is the Deputy Division Director of the Division of Biometrics IX at CDER/FDA. She earned her PhD from Cornell University and certificate in Strategic Decision and Risk Management from Stanford University. Prior to joining FDA in 2012, Dr. Rodriguez supported a variety of therapeutic areas in industry. Her work at FDA has covered issues in oncology, hematology, meta-analyses, evaluation of biomarker and PRO/COA endpoints, survival analyses, and adaptive designs, and she recently served as co-organizer of the FDA-AACR-ASA Workshop on Overall Survival. She co-leads the Benefit-Risk Assessment Planning (BRAP) Taskforce within the ASA Biopharm Safety Working Group and is part of several internal FDA scientific working groups.

Speaker(s)

Panelist

Timothy Cloughesy, MD

Professor of Neurology, Director, UCLA Brain Tumor Center
UCLA, United States

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Panelist

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Panelist

Elyse Katz, PhD

Senior Product Management Support, Warfighter Brain Health PMO, USAMMDA
Tunnell Government Services, Inc., United States

Elyse Katz, PhD, supports the US Department of Defense's efforts to increase the medical readiness of active-duty service members through the development and deployment of psychological health and traumatic brain injury diagnostics and therapeutics. To facilitate this work, she leverages her background in biomarker and clinical development in Neuroscience, as well as experience working collaboratively with colleagues from other government agencies, academic institutions, and industry partners.

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Associate Director for Statistical Science and Policy, OB, OTS, CDER
FDA, United States

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3:45 PM — 4:00 PM

Next Steps and Closing Remarks

4:00 PM — 4:00 PM

Summit Adjourns