13th Annual FDA/AdvaMed Medical Devices & Diagnostics Statistical Issues Conference
Washington Marriott at Metro Center | Washington, DC
April 23 – 24, 2020

Thursday, April 23, 2020

8:45 – 9:15 am  Registration Check-In and Breakfast

9:15 – 9:20 am  Welcome and Introduction of Keynote Speaker

9:20 – 10:00 am  Keynote Address
Dr. William Maisel, Chief Medical Officer and Director, Office of Product Evaluation and Quality, FDA/CDRH

10:00 – 10:30 am  Break

10:30 – 12:00 pm  What's New in Medical Device Development

Co-organizers
Saryet Kucukemiroglu, FDA
Mourad Atlas, FDA
Vicki Petrides, Abbott
Jim Lesko, DePuy Synthes

Speakers
Ram Tiwari, PhD, FDA/CDRH
Scott Berry, PhD, Berry Consultants
Pablo Morales, MD, FDA/CDRH
Roseann White, The Third Opinion

12:00 – 1:30 pm  Lunch

1:30 – 3:00 pm  Framework and Methods for Using External Evidence: Leveraging Real World Data and Historical Data in Medical Device Regulatory Decision-Making for Both Therapeutic and Diagnostic Devices

Co-organizers
Yongping Yan, FDA
Arianna Simonetti, FDA
Ge Guo, Roche
Trina Patel, Edwards

Speakers
Dr. Vandana Bathia, FDA
3:00 – 3:30 pm  Break

3:30 – 5:00 pm  Global Harmonization – International Regulations Impacting Statistical Practices

Co-organizers
Manasi Sheth, FDA
Manuela Buzoianu, FDA
Robert Neher, Zimmer Biomet
Shelley Walters, 3M

Speakers
Kenneth Cavanaugh, PhD, Office of Health Technology 2, OPEQ/CDRH/FDA
Mailin Hesse, Abbott Germany
Jaap Laufer, MD, PharmD, Emergo

5:00 – 6:00 pm  Poster Session and Networking Reception

Friday, April 24, 2020

8:00 – 8:30 am  Breakfast

8:30 – 4:30 pm  Concurrent Sessions - Therapeutic Device Track and Diagnostics Track

Therapeutic Device Track

8:30 – 8:45 am  Welcome Remarks

8:45 – 10:15 am  Long Term Safety Assessment

Co-organizers
Adrijo Chakraborty, FDA
Ted Lystig, Medtronic

Speakers
Nelson Lu, FDA/CDRH
Tim Hanson, Medtronic
Scott Snyder, Cook Medical

10:15 – 10:30 am  Break

10:30 – 12:00 pm  Outcome-Free Study Design
Co-organizers
Sutan Wu, FDA
Peter Lam, Boston Scientific

Speakers
Chenguang Wang, Johns Hopkins University
Heng Li, FDA
Jeremy Gorelick, Edwards Lifesciences
Songtao Jiang, Boston Scientific

12:00 – 1:15 pm   Lunch

1:15 – 2:45 pm   Two-Phase Study Design

Co-organizers
Bin Wang, FDA
Pei Li-Medtronic Li, Medtronic

Speakers
Chia-Wen (Kiki) Ko, CDRH/FDA
Ming Tan, Georgetown University
Tyson Rogers, NAMSA, Inc.

2:45 – 3:00 pm   Break

3:00 – 4:30 pm   Clinical Outcome Assessment (COA)

Co-organizers
Xuefeng Li, FDA
Greg Ginn, Abbott

Speakers
Michelle Tarver, FDA/CDRH/OST
Daniel Serrano, Pharmerit
Samuel F. Sears, East Carolina University,

4:30 pm   Adjournment

Diagnostics Track

8:30 – 8:45 am   Welcome Remarks

8:45 – 10:15 am   New Developments in Digital Health Involving Artificial Intelligence/Machine Learning

Co-organizers
Jessie Moon, FDA
Susan Gawel, Abbott

**Speakers**
Mozzi Etemadi, MD, PhD, Northwestern University Feinberg School of Medicine  
Gail Kongable, Alere  
Arkendra De, PhD, FDA/CDRH/OPEQ

10:15 – 10:30 am  Break

10:30 – 12:00 pm  Emerging Intended Uses for Diagnostic Devices: Risk Stratification, Workflow Prioritization, and Shortened Reading Time

**Co-organizers**
Lan Huang, FDA  
Ruixiao Lu, Exact Sciences

**Speakers**
Mike Bonham, MD, PhD, Proscia  
Jim Whitmore, Exact Sciences  
Jessie Moon, FDA/CDRH/OPEQ/OCEA/DCEAII  
Feiming Chen, FDA/CDRH/OPEQ/OCEA/DCEAII

12:00 – 1:15 pm  Lunch

1:15 – 2:45 pm  New Trends in Technology and Statistical challenges

**Co-organizers**
Sunghee Kim, FDA  
Darcy Vavrek, Illumina

**Speakers**
Zhiheng Xu, FDA  
Meijuan Li, Foundation Medicine  
Kristen Meier, Illumina

2:45 – 3:00 pm  Break

3:00 – 4:30 pm  Analytical Study Issues: CLSI Guidelines Update and Establishing Performance Criterion

**Co-organizers**
Xiaoqin Xiong, FDA
Zhen Jiang (CBER), FDA
Jing Lu, Illumina

Speakers

Sub-session 1: CLSI Guidance Update
Marina Kondratovich, FDA/CDRH
Shuguang Huang, Stat4ward, LLC

Sub-session 2: Performance Criteria
Chunrong Cheng, FDA/CBER
Gerry Gray, Data-Fi, LLC

4:30 pm  Adjournment