



Scientific Program

February 23-24, 2026

Hilton Washington DC/Rockville Hotel & Executive Meeting Center

1750 Rockville Pike, Rockville, MD 20852

DAY 1 — Monday, February 23, 2026

8:00 AM – 8:45 AM

Breakfast

8:35 AM – 9:00 AM

Inauguration

9:00 AM – 10:00 AM

Keynote Address

One Trial – Multiple Targets! Makes Sense But How?

Javed Butler, *President*, Baylor Scott and White Research Institute
Senior Vice President, Baylor Scott and White Health

10:00 AM – 10:15 AM

Break

10:15 AM – 11:45 AM

Scientific Session I

Innovative Trial Designs: Exploring Multiple Indications Within a Single Study

10:15 AM – 10:30 AM — **Multi-Organ outcome study**

Yongming Qu, *Vice President, Statistics*, Eli Lilly

10:30 AM – 10:45 AM — **Approaches to move from a narrow indication specific composite endpoint to a more holistic assessment of efficacy in Cardio Renal Metabolic trials**

Stefan Hantel, *Expert Statistician*, Boehringer Ingelheim

10:45 AM – 11:00 AM — **TRIUMPH-OUTCOMES**

Cem Kayhan, *Associate Vice President, Development*, Eli Lilly

11:00 AM – 11:15 AM — **Causal mediation analysis in metabolic disease**

Jesper Madsen, *Director, Statistics*, Novo Nordisk

11:15 AM – 11:30 AM — **Going beyond one trial – utilization of data across development programmes**

Sille Esbjerg, *Director, Statistics*, Novo Nordisk

Lene Sommer Vestergaard, *Associate Director, Statistics*, Novo Nordisk

11:30 AM – 11:45 AM— **Q&A**

11:45 AM – 1:00 PM

Lunch

1:00 PM– 2:15 PM

Scientific Session II

Active Comparator in Obesity Trials

1:00 PM– 1:20 PM— **Active comparator studies for weight management with a case study**

Anna Batorsky, *Advisor, Statistics*, Eli Lilly

1:20 PM– 1:40 PM— **Applying the estimand framework to Non-Inferiority trials**

Bharani Dharan, *Executive Director, Statistics*, Novartis

1:40 PM– 2:00 PM— **Working Group Update**

Jennifer Schumi, *Director, Statistics, Amgen*

Jiawen Zhu, *Senior Principal Statistical Scientist, Statistics, Genentech*

2:00 PM– 2:15 PM — **Q&A**

2:15 PM – 3:15 PM

Scientific Session III

Treat-to-Target in Obesity

2:15 PM– 2:55 PM- **Treat to target in obesity management: The Why and how?**

Volker Schnecke, *Senior Real-World Evidence Manager, Novo Nordisk*

Abd Tahrani, *Vice President, Development, Amgen*

2:55 PM– 3:05 PM - **Working Group Update**

Cassie Burns, *Senior Director, Statistics, Amgen*

3:05 PM – 3:15 PM — **Q&A**

3:15 PM – 3:30 PM

Break

3:30 PM – 5:00 PM

Regulatory Dialogue I

Talk to Regulators

Moderator:

Tim Friede, *Professor of Biostatistics, University Medical Center Göttingen*

Panelists:

Aliza Thompson, *Director, Division of Cardiology and Nephrology Office of Cardiology, Hematology, Endocrinology, & Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)*

Charu Gandotra, *Deputy Director, Division of Cardiology and Nephrology, Office of Cardiology, Hematology, Endocrinology, & Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)*

John Sharretts, *Director, Division of Diabetes, Lipid Disorders and Obesity (DDL0), Office of Cardiology, Hematology, Endocrinology, & Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)*

Robert Abugov, *Senior Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)*

Raymond Soccio, *Lead Medical Officer, Division of Diabetes, Lipid Disorders, and Obesity (DDL0), Office of Cardiology, Hematology, Endocrinology, & Nephrology, C Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)*

Jialu Zhang, *Supervisory Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)*

5:00 PM – 7:00 PM

Reception

DAY 2 — Tuesday, February 24, 2026

8:00 AM – 8:45 AM

Breakfast

8:45 AM – 9:00 AM

Inauguration

9:00 AM – 10:00 AM

Keynote Address

Statistical Challenges in Developing Products Treating Metabolic Diseases

Mark Rothmann, *Director, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, Food and Drug Administration (FDA)*

10:00 AM – 10:15 AM

Break

10:15 AM – 11:40 AM

Scientific Session IV

Covariate Adjustment in Cardiometabolic Health (CMH) Trials

10:15 AM – 10:30 AM — **Covariate-adjusted log-rank test: guaranteed efficiency gain and universal applicability**

Marlena Bannick, *Biostatistician, Seattle Children's Research Institute*

10:30 AM – 10:55 AM — **Outcome Working Group update**

Yongming Qu, *Vice President, Statistics, Eli Lilly*

Henrik Ravn, *Senior Director, External Collaboration & Experimentation, Novo Nordisk*

10:55 AM – 11:20 AM — **The effect of covariate adjustment for Cox regression in Cardiovascular Outcome (CVOT) trials**

Ran Bi, *Associate Director, Statistics, Novartis*

11:20 AM – 11:40 AM — **Q&A**

11:40 AM – 1:00 PM

Lunch

1:00 PM – 2:30 PM

Scientific Session V

Artificial Intelligence (AI), Digital Health, and Real-World Evidence (RWE) in CMH

1:00 PM – 1:15 PM — **X-Y-Z framework for Modernizing Drug Development with AI**

Yong Chen, *Professor of Biostatistics at Department of Biostatistics, Epidemiology, and Informatics (DBEI), University of Pennsylvania, Perelman School of Medicine*

1:15 PM – 1:30 PM — **AI in cardiovascular disease**

Hongtu Zhu, *Kenan Distinguished Professor of Biostatistics, Statistics, Radiology, Computer Science and Genetics, University of North Carolina at Chapel Hill*

1:30 PM – 1:45 PM — **Beyond fixed thresholds: optimizing summaries of wearable device data**

Irina Gaynanova, Associate Professor, Biostatistics, School of Public Health, University of Michigan

1:45 PM – 2:00 PM — **Artificial Intelligence to Automate Clinical Event Adjudication in Global Randomized Trials**

Pablo Marti Castellote, Research Fellow in Medicine, Brigham and Women's Hospital

2:00 PM – 2:15 PM — **Impact of GLP-1 Discontinuation on HbA1c and Weight in Real-World T2D Patients**

Christophe Tchakoute, Senior Data Scientist, Product Development Data Sciences, Genentech

2:15 PM – 2:30 PM — **Q&A**

2:30 PM – 2:45 PM

Break

2:45 PM – 3:45 PM

**Regulatory Dialogue II
Talk to Regulators**

Moderators:

George Kordzakhia, Senior Director, Statistics, AstraZeneca

Godwin Yung, Statistical Methodology Lead, Roche-Genentech

Panelists:

Lisa Yanoff, Deputy Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)

Mark D Rothmann, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, U.S. Food and Drug Administration (FDA)

Yun Wang, Deputy Director, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, U.S. Food and Drug Administration (FDA)

Yoonhee Kim, Lead Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, U.S. Food and Drug Administration (FDA)

William Koh, Senior Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, Office of Translational Studies, U.S. Food and Drug Administration (FDA)

Jordon Pomeroy, Senior Medical Officer, Division of Cardiology and Nephrology, Office of Cardiology, Hematology, Endocrinology, and Nephrology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)

3:45 PM – 4:00 PM

Closing