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– 3:00 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

3:00 PM– 3:15 PM - **Working Group Update**
Cassie Burns, *Senior Director, Statistics,* Amgen

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 (DDLO), 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 (DDLO), 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**