Monday, February 26, 2024

9:00 AM – 10:10 AM Session 1: Clinical Pharmacology Considerations

9:00 AM – 9:05 AM Introduction and Welcome
Yow-Ming C. Wang, PhD, U.S. Food & Drug Administration

9:05 AM – 9:15 AM Precision Dosing: From Aspiration to Application
Issam Zineh, PharmD, MPH, FCP, FCCP, U.S. Food & Drug Administration

9:15 AM – 9:35 AM Scientific & Technical Perspective
Diane R. Mould, PhD, Projections Research Inc.

9:35 AM – 9:55 AM Drug Developer’s Perspective
Honghui Zhou, PhD, FCP, FAAPS, Jazz Pharmaceuticals

9:55 AM – 10:10 AM Question & Answer
Yow-Ming C. Wang, PhD, U.S. Food & Drug Administration

10:10 AM – 10:20 AM Coffee Break

10:20 AM – 11:45 PM Session 2: TDM in Clinical Practice

10:20 AM – 10:50 AM Proactive TDM: Its Time has Come
Adam Cheifetz, MD, Harvard Medical School, Beth Israel Deaconess Medical Center

10:50 AM – 11:10 AM TDM in Rheumatology
Sandra Garces, MD, PhD, Amgen Inc

11:10 AM – 11:30 AM TDM for the Well-Being of Children
Rachel Chevalier, MD, Children’s Mercy Kansas City

11:30 AM 11:45 AM Question & Answer
Amy Rosenberg, MD, EpiVax, Inc.
11:45 AM – 12:45 PM  Lunch

12:45 PM – 1:40 PM  Session 3: Health Economics

12:45 PM – 1:05 PM  HEOR Data on TDM of Biologics
Sean Gavan, PhD., MSc, The University of Manchester

1:05 PM – 1:25 PM  Translation of HEOR Findings on TDM of Biologics in the US Healthcare Landscape
Mark Trusheim, MS, BS, MIT NEWDIGS

1:25 PM – 1:40  Question & Answer
Sophie Shubow, PhD, U.S. Food & Drug Administration

1:40 PM – 1:45 PM  Coffee Break

1:45 PM – 3:00 PM  Session 4: Enabling Technologies

1:45 PM – 2:05 PM  Experience from TDM in Small Molecules
Joseph Kotarek, PhD U.S. Food & Drug Administration

2:05 PM – 2:25 PM  TDM Operations: Perspective from a European CRO
Theo Rispens, PhD, Sanquin

2:25 PM – 2:45 PM  Developing FDA-Cleared TDM Tests for Biologics – A Manufacturer’s Perspective
Kurtis R. Bray, PhD, ProciseDx

2:45 PM – 3:00 PM  Question & Answer
Michele Gunsior, PhD, Astria Therapeutics

3:00 PM – 3:10 PM  Coffee Break

3:10 PM – 4:20 PM  Panel Discussion
Moderated by Michael Partridge, PhD, Regeneron Pharmaceuticals, Inc.
Panelists:
Diane R. Mould, PhD, Projections Research Inc.
Honghui Zhou, PhD, FCP, FAAPS, Jazz Pharmaceuticals
Adam Cheifetz, MD, Harvard Medical School, Beth Israel Deaconess Medical Center
Sandra Garces, MD, PhD, Amgen Inc
Rachel Chevalier, MD, Children’s Mercy Kansas City
Sean Gavan, PhD., MSc, The University of Manchester
Mark Trusheim, MS, BS, MIT NEWDIGS
Joseph Kotarek, PhD U.S. Food & Drug Administration
Theo Rispens, PhD, Sanquin
Kurtis R. Bray, PhD, ProciseDx
Issam Zineh, PharmD, MPH, FCP, FCCP, U.S. Food & Drug Administration
Ping Ji, PhD, U.S. Food & Drug Administration

4:20 PM – 4:30 PM  Closing Remarks
Yow-Ming C. Wang, Ph.D, U.S. Food & Drug Administration