AGENDA

7:30 a.m. – 8:30 a.m. Registration and Continental Breakfast

8:30 a.m. – 8:50 a.m. **Welcome and Introduction by Chairperson**

- **Jess Rabourn,** Founder/CEO, WideTrial, Inc.

8:50 a.m. – 9:50 a.m. **The Foundations of EAPs**

In this session, you'll learn about the development of EAPS, including historical business practices; current regulations; definition of terms; strategic considerations in implementing integrated research and treatment programs; important new state and federal legislatives; and international developments.

- **David Farber,** Senior Partner, King & Spalding
- **Karen Frascello,** Vice President of Business Development, Caligor
- **Tim Miller, MD,** Vice President, Head of North America Medical Affairs, Sanofi/Genzyme

9:50 a.m. – 10:15 a.m. Networking Break

10:15 a.m. – 12:15 p.m. **Handling the Challenges of EAPs**

This panel will cover commercial hazards of EAPs — both real and imaginary; medical and bioethical considerations; operational planning: objectives, execution, and scale; and reimbursement and sustainability of large EAPs.

- **Heather Manna,** Associate Director, Expanded Access, Tesaro Bio, Inc.
- **Tom Watson,** Consultant, Pre-Approval Access, TW Consulting
- **Hank Mansbach, MD,** VP Clinical Development, Ultragenyx
- **Kevin Weatherwax,** Adjunct Associate Clinical Professor, Co-Chair, Expanded Access Oversight Committee, University of Michigan Medical System
- **Karen Frascello,** Vice President of Business Development, Caligor
- **David Farber,** Senior Partner, King & Spalding

12:15 p.m. – 1:30 p.m. Luncheon

1:30 p.m. – 2:30 p.m. **Maximizing the Value of EAPs**

In this session, you'll hear a discussion of a case history of data uses from large EAPs; emerging frameworks for Real World Data (RWD) collection and pragmatic trials; and integrating sample collection and multi-omics for clinical discovery.

- **Hank Mansbach, MD,** VP Clinical Development, Ultragenyx
- **Jess Rabourn,** Founder/CEO, WideTrial, Inc.

- **Kevin Weatherwax,** Adjunct Associate Clinical Professor, Co-Chair, Expanded Access Oversight Committee, University of Michigan Medical System

2:30 p.m. – 3:15 p.m. **Can EAPs Improve the Drug Development Process in Breakthrough Diseases?**

This is an interactive session in which you and experts in the EAP field will discuss how EAPs can improve the current drug development process for serious diseases.

3:15 p.m. – 3:30 p.m. Networking Break

3:30 p.m. – 5:00 p.m. **New Business Models for Inclusivity, Wider Access to Patients, and Data Utilization**

This session covers commercial feasibility and cost recovery; patient-centric resources; crowd-sourced data; and business-to-consumer sequencing and design.

- **Heather Manna,** Associate Director, Expanded Access, Tesaro Bio, Inc.
- **Tom Watson,** Consultant, Pre-Approval Access, TW Consulting
- **Tim Miller, MD,** Vice President, Head of North America Medical Affairs, Sanofi/Genzyme
- **Jess Rabourn,** Founder/CEO, WideTrial, Inc.

5:00 p.m. Adjournment

5:15 p.m. – 6:30 p.m. Networking Reception