ISCTM
International Society for CNS Clinical Trials and Methodology

From Real World Data to Real World Evidence – Implementation of Regulatory Guidance in Drug Development

February 15, 2023

Co-Chairs: Mike Davis, M.D., Ph.D. and Ibrahim Turkoz, Ph.D.

Introduction

- First ISCTM session specifically devoted to Real World Evidence (RWE)
- Regulatory environment for using Real World Data (RWD) and RWE developing rapidly
- Methods for collecting data (e.g., digital health technologies) as well as linking electronic health data sources (e.g., electronic health records, registries, claims databases) are evolving
- **Session designed to discuss regulatory guidance regarding RWD/RWE, highlight challenges and solutions by discussing case examples, and discuss a proposed enrollment strategy for RWE studies**

Schedule

- **John Concato, MD, MPH** (FDA): FDA's Real-World Evidence Program
- **Motiur Rahman, MPharm, MS, PhD** (FDA): Real-World Evidence: PDUFA VII Commitments and FDA Use Cases
- **Karl Broich, MD** (BfArM): Gathering and Use of RWE in a European Setting
- **Ibrahim Turkoz, PhD** (Janssen R&D): Recruitment Strategy for Prospective Observational Studies to Mimic Randomization: Up-front Matching
- **Larry Alphs, MD, PhD** (Denovo Biopharma): Enhancing CNS Product Labels with Pragmatic Trials: Challenges, Solutions, and Outcomes that Support the Road to RWE
- Discussants: **Sam Wilkinson, MD** (Yale) and **Andrew Potter, PhD** (FDA)
- **Panel Discussion**