Real-World Evidence Webinar: Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products Guidance for Industry

Real-World Evidence Guidance Webinar Series

April 13, 2023

2-3 PM ET

Speaker Biographies

Speakers

John Concato, MD, MPH, MS
Associate Director for Real-World Evidence Analytics, OMP, CDER, FDA

Dr. John Concato is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), FDA. As an internist and epidemiologist, Dr. Concato seeks to enhance policies related to drug development and regulatory review. His responsibilities include a focus on real-world evidence (RWE) and involve work developing internal Agency processes for evaluating RWE, interacting with external stakeholders regarding RWE, supporting RWE demonstration projects and guidance development, and serving as the Chair of the RWE Subcommittee. Prior to joining FDA, his career focused on generating research as an independent investigator, research center director, and Professor of Medicine at Yale University School of Medicine and the U.S. Department of Veterans Affairs (VA); he also was one of two founding principal investigators of the VA Million Veteran Program genomic mega-biobank. He received doctoral and master's degrees from New York University and a master's degree in Public Health from Yale University.

Pallavi Mishra-Kalyani, PhD
Supervisory Mathematical Statistician in the Division of Biometrics V, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Pallavi Mishra-Kalyani is a Supervisory Mathematical Statistician in the Division of Biometrics V, Office of Biostatistics which supports Office of Oncology Drugs at the Center for Drug Evaluation and Research (CDER). Since joining the FDA in 2015, Dr. Mishra-Kalyani has contributed to the efforts to understand and address the statistical issues related to the potential use of external controls, Real World Data, and Real-World Evidence for regulatory purposes. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design. She has organized and participated at several statistics and oncology workshops, conferences, and working groups on these topics. Dr. Mishra-Kalyani received her doctorate in Biostatistics from Emory University, her master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University, and her bachelor's degree from MIT.

Motiur Rahman, PhD, MPharm, MS
Senior Epidemiologist at Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Motiur Rahman is a Senior Epidemiologist at Real-World Evidence (RWE) Analytics in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). His responsibilities include developing guidance, improving internal Agency processes, stakeholder engagement, collaborating on Agency-funded demonstration projects, and providing consultancy on RWE study submissions. He joined FDA in April 2022 after a 10+ years of working experience in academia and industry in conducting RWE studies across a wide range of therapeutic areas. Dr. Rahman received his Pharmacy degree from University of Dhaka, Bangladesh, his doctoral degree in Pharmacoepidemiology and master's degree in Statistics from Auburn University, AL.

Moderator

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler, is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.