Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice

Real-World Data Guidance Webinar Series

November 22, 2024

1 – 1:45 p.m. Eastern Time

Speaker Biographies

Speakers

John Concato, MD, MPH, MS
Associate Director for Real-World Evidence Analytics
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (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.

Leonard Sacks, MBBCh
Associate Director
Clinical Methodologies, OMP, CDER, FDA

Dr. Sacks received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa, and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. Dr. Sacks holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.

Heather Stone, MPH
Health Science Policy Analyst
Clinical Methodologies, OMP, CDER, FDA

Heather Stone is a Health Science Policy Analyst at the U.S. Food and Drug Administration, in the Clinical Methodologies Group of the Office of Medical Policy, Center for Drug Evaluation and Research. Ms. Stone joined the FDA upon completing her Master's in Public Health (Concentration: Epidemiology) from the University of Maryland School of Public Health in 2012. She has led the CURE ID program since 2013, which is a joint FDA and NCATS/NIH drug repurposing initiative. Ms. Stone's research focus is on the creation of policies that will encourage drug development for infectious diseases and other diseases with high unmet medical need. She applies her policy expertise to issues related to drug repurposing and innovation in clinical trial design.

Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the Food and Drug Administration

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her JD *magna cum laude* from Georgetown University Law Center. She is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.