Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry

Real-World Data Guidance Webinar Series

January 28, 2022

1-2 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.

Kerry Jo Lee, MD

Associate Director for Rare Diseases, Rare Diseases Team, Division of Rare Diseases and Medical Genetics, OND, CDER, FDA

Dr. Kerry Jo Lee is the Associate Director for Rare Diseases in the Division of Rare Diseases and Medical Genetics, Office of New Drugs (OND), CDER. In this role she leads the Rare Diseases Team, a multidisciplinary rare disease programming and policy team that works to promote their mission to facilitate, support, and accelerate the development of drugs and therapeutic biologics for rare diseases. Dr. Lee is a pediatric gastroenterologist/hepatologist who joined the FDA as a medical officer in 2014 with the former the Division of Gastroenterology and Inborn Errors Products, OND, CDER. Dr. Lee then moved to a position as a clinical advisor for the Office of New Drug Policy, CDER, where she served as a lead in the areas of benefit-risk assessment, modernization efforts (including the integrated review for marketing applications), and real-world data/evidence programming before serving in her current position.

Ansalan Stewart, PhD

Health Science Policy Analyst, Division of Clinical Trial Quality, OMP, CDER, FDA

Dr. Ansalan Stewart currently works within the FDA CDER Office of Medical Policy's Division of Clinical Trial Quality as a Health Science Policy Analyst. Dr. Stewart has extensive experience in policy development, implementation, and evaluation related to the biological sciences and medical product development. She served as the technical lead to develop the FDA Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products draft guidance with FDA subject matter experts. Dr. Stewart completed her doctoral and post-doctoral work in neuroscience at the University of Tennessee Health Science Center and George Washington University, respectively.

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.