REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products

Real-World Data Guidance Webinar Series

February 11, 2022

11-12 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.

Tala Fakhouri, PhD, MPH

Associate Director for Policy Analysis, Office of Medical Policy Initiatives, OMP, CDER, FDA

Dr. Tala Fakhouri is the Associate Director for Policy Analysis in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), FDA. Dr. Fakhouri's responsibilities are focused on developing policies for drug development and regulatory decision making with emphasis on real-world data and real-world evidence (RWD/RWE), data science, artificial intelligence, and digital health technologies. Prior joining FDA in October of 2020, Dr. Fakhouri served as a Senior Health Scientist and Chief Statistician for the CDC's flagship population survey, the National Health and Nutrition Examination Survey (NHANES). Additionally, she served on the CDC's National Center for Health Statistics Disclosure Review Board, the Cancer Moonshot Data Science Workgroup, and co-led the Federal Committee for Statistical Methodology (FCSM) Nonresponse Bias Subcommittee. Prior to joining NHANES, Dr. Fakhouri served as an Epidemic Intelligence Service Officer with the CDC. She earned a doctoral degree in oncological sciences from The Huntsman Cancer Institute at the University of Utah, an master's degree in Epidemiologic and Biostatistical Methods from the Johns Hopkins University School of Public Health, and a postdoctoral fellowship in molecular biology and genetics from Harvard University.

Stefanie Kraus, JD, MPH

Senior Regulatory Counsel, Office of Regulatory Policy, CDER, FDA

Stefanie Kraus is a Senior Regulatory Counsel in the Center for Drug Evaluation and Research's (CDER) Office of Regulatory Policy (ORP) at the Food and Drug Administration (FDA). She received her juris doctor from Brooklyn Law School and her master's degree from the Harvard T.H. Chan School of Public Health. In her position, Ms. Kraus leads ORP's work on clinical trials and drug development standards, real-world evidence, regulatory science research, and artificial intelligence. Ms. Kraus works on developing policy and regulatory standards and serves on several key steering committees at CDER, including the Real-World Evidence Subcommittee of the Medical Policy Program and Review Counsel, the Artificial Intelligence Steering Committee, the Research Governance Council, the Complex Innovative Trial Design Steering Committee, and the Model Informed Drug Development Steering Committee. Ms. Kraus also serves as one of the leads for ORP's COVID-19 pandemic response efforts, including policy development around the continuing conduct of clinical trials, development of therapeutics to treat or prevent COVID-19, and Emergency Use Authorizations.

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.