



# **Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products**

Real-World Data Guidance Webinar Series

Thursday, May 30, 2024

2 – 2:45 PM Eastern Time

## **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, a 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.**

#### **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.