Data Standards for Drug and Biological Product Submissions Containing Real-World Data

Real-World Evidence Webinar Series

December 3, 2021

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.

Gideon Scott Gordon, PhD

Senior Health Informatics Officer, Office of Strategic Programs, CDER, FDA

Dr. Scott Gordon is a Senior Health Informatics Officer for the Office of Strategic Programs in the Center for Drug Evaluation and Research at FDA since 2016. Dr. Gordon is responsible for a range of activities to standardize data for clinical research, submissions to FDA, and post-market surveillance. A significant aspect of Dr. Gordon's work includes a focus on "real-world data" derived from health information technology and other non-traditional sources for use as an adjunct to data from traditional clinical trials and current pharmacovigilance methods. In parallel, Dr. Gordon also works to standardize pharmaceutical quality and manufacturing data for submission to FDA. Previously, Dr. Gordon worked at the Association for State and Territorial Health Officials (ASTHO) from 2011 with a focus on public health informatics, including interactions between federal, state, and local public health information systems and healthcare information technology such as the CDC's National Syndromic Surveillance System. He entered the public health domain in 2005 as a subcontractor for the Department of Homeland Security for public health emergency preparedness activities with the Massachusetts Department of Public Health. Prior to a post-doctoral position at the Whitehead Institute for Biomedical Sciences, Dr. Gordon received his core scientific training with bachelor's

degree in Biology from Case Western Reserve University and a doctorate in Molecular Microbiology from Tufts University Medical School.

Massoud Motamed, PhD, MS
Biology Reviewer, Office of Tissue and Advanced Therapies, CBER, FDA

Dr. Massoud Motamed is currently a biology reviewer in the Gene Therapy Branch, Office of Tissue and Therapeutic Advances, Center for Biologic Evaluation and Research, FDA. Dr. Motamed began his career as a pharmaceutical investigator with the Office of Regulatory Affairs, FDA where he was awarded the FDA Outstanding Service Award. Subsequently, he worked in the pharmaceutical industry, leading compliance for a global generic company before returning to the FDA as a health informatics officer in the Office of Strategic Programs (OSP), Center for Drug Evaluation and Research. While in OSP, he combined his technical expertise in clinical research and regulatory submission data and contributed to activities focused on the use of real-world data derived from non-traditional sources. Dr. Motamed received his master's degree in Organic Chemistry from the University of California at Berkeley and his doctorate in Biochemistry from the University of Texas Southwestern.

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.