

Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry

Real-World Evidence Webinar Series

November 4, 2021

1:30-2:30 pm ET

Speaker Biographies

Speakers

Michael Blum, MD, MPH

Deputy Director, Office of Pharmacovigilance and Epidemiology, OSE, CDER, FDA



Dr. Michael Blum is currently Deputy Director, Office of Pharmacovigilance and Epidemiology in FDA CDER. He is a pediatric infectious diseases specialist. Dr. Blum worked as a medical reviewer in the CDER Division of Anti-Infective Drug Products, followed by over 20 years in the pharmaceutical industry in a variety of vaccine and safety leadership positions. He has experience in industry and the FDA with the use of real-world data to assess the safety of drugs and

biologics and currently represents the CDER Office of Surveillance and Epidemiology on the FDA RWE Program.

John Concato, MD, MPH, MS

Associate Director for Real-World Evidence Analytics, OMP, CDER, FDA



Dr. Concato is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). After conducting clinical research studies for more than 25 years as an independent investigator and research center director at Yale University & the Department of Veterans Affairs, he now develops, coordinates, and implements medical policy programs and strategic initiatives, with a focus on real-world evidence (RWE). These efforts include

overseeing RWE guidance development and demonstration projects, as well as engaging external stakeholders and contributing to the review of RWE submissions, in support of the agency's evaluation of RWE as mandated by the 21st Century Cures Act.

Wei Hua, MD, PhD, MHS, MS

Supervisory Associate Director in Oncology and RWE, Division of Epidemiology I, Office of Pharmacovigilance and Epidemiology, OSE, CDER, FDA



Dr. Wei Hua is currently Supervisory Associate Director in Oncology and RWE, Division of Epidemiology-I in the Office of Surveillance and Epidemiology, CDER, FDA. She received her medical degree from China and PhD from the Johns Hopkins School of Public Health. Her areas of expertise include infectious disease epidemiology and pharmacoepidemiology with experience in both experimental and observational studies using primary and secondary

data in the U.S. and through multi-site international collaborations. Over the past ten years, Dr. Hua has held multiple roles in the FDA centers for biologics and drugs leading and overseeing epidemiological research and review in the regulatory setting.

Natasha Pratt, PhD

Acting Team Leader, Senior Epidemiologist, Division of Epidemiology II, Office of Pharmacovigilance and Epidemiology, OSE, CDER, FDA



Dr. Pratt is a Senior Epidemiologist and Acting Team Leader at the Division of Epidemiology II, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA). She provides expertise in evaluating the quality of real-world evidence (RWE) generated by observational studies that is used to support the safety and effectiveness of anti-infective, antiviral, ophthalmology, anesthesia, analgesia, and addiction products. She

received her bachelor's degree in Pharmacy from National Taiwan University, doctoral degree in Pharmacoepidemiology from the University of Florida and completed a postdoctoral fellowship in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, Harvard Medical School, before joining the FDA. She has an in-depth understanding of real-world data (RWD) through hands-on experience with multiple research projects using various types of RWD, including electronic medical records from tertiary care facilities, national disease and device registries, and both public and private administrative claims data.

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.