

Lessons Learned from Trial Replication Analyses: Findings from the DUPLICATE Demonstration Project

Virtual Public Webinar

May 10, 2022 | 12:00 pm – 2:30 pm ET

Speaker Biographies



John Concato is the Associate Director for Real-World Evidence Analytics in the Office of Medical Policy (OMP) at the Center for Drug Evaluation and Research (CDER), US Food and Drug Administration. In seeking to enhance policies related to drug development and regulatory review in CDER, his responsibilities include serving as the Chair of RWE Subcommittee, supporting RWE guidance development and demonstration projects, interacting with external stakeholders regarding RWE, and developing internal Agency processes related to RWE. Prior to joining FDA in 2019, his career focused on generating research as an independent investigator and research center director at Yale University School of Medicine and the U.S. Department of Veterans Affairs (VA), including serving as one of two founding principal investigators of the VA Million Veteran Program. He received M.D. and M.S. degrees from New York University and an M.P.H. degree from Yale University.



Issa J. Dahabreh is Associate Professor in the Departments of Epidemiology (primary) and Biostatistics (secondary) at the Harvard T.H. Chan School of Public Health, and Section Head for Epidemiology and Data Science at the Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology at Beth Israel Deaconess Medical Center. His research focuses on the development and assessment of novel methods for causal inference using data from diverse sources.



Steve Goodman, MD, MHS, PhD, is Associate Dean for Clinical and Translational Research and Professor of Epidemiology & Population Health and of Medicine at the Stanford University School of Medicine. He directs the Stanford Program on Research Rigor and Reproducibility (SPORR) and is co-founder and co-director of the Meta-research Innovation Center at Stanford (METRICS), a group dedicated to studying and improving the reproducibility and efficiency of biomedical research. He is Director of Graduate Studies in the Stanford Dept. of Epidemiology, directs Stanford's CTSA workforce development program and is associate director of KL2 CTSA fellowship.

His research areas are in scientific and statistical inference, with a focus on what is now called research reproducibility and on Bayesian methods. He serves as chair of the PCORI Methodology Committee, senior statistical editor at the Annals of Internal Medicine, and is scientific advisor to the national Blue Cross-Blue Shield technology assessment program. He was awarded the 2016 Spinoza Chair in Medicine from the University of Amsterdam for his work in inference, the 2019 Lilienfeld award from the American College of Epidemiology for his lifetime contributions to the field of epidemiology and is an elected member of the National Academy of Medicine.



Skip Olson, ScD, is currently the Global Head of Integrated Evidence Strategy and Innovation at Novartis. As such, he is responsible for promoting the very best in research methodology and applications of Real World and other Evidence across all therapeutic areas and around the globe to drive better decision making. He comes from a background in HE&OR where he has led the use of RWE to transform the generation of patient insights and value for money assessments. He earned a ScD in Biostatistics from Harvard University and has worked in the pharmaceutical industry for nearly 30 years.



LCDR Kenneth Quinto M.D., M.P.H. is the Senior Medical Advisor in the Real World Evidence Analytics Staff in the Office of Medical Policy at FDA's Center for Drug Evaluation and Research. He oversees demonstration projects intended to support the agency's evaluation of real world evidence, evaluates real world evidence use cases, and contributes to medical policy development mandated by the 21st Century Cures Act. LCDR Quinto has held various positions at different U.S. Department of Health and Human Services' agencies including as a medical officer at FDA's Office of Pediatric Therapeutics, a medical officer/claims analyst at the Centers for Medicare and Medicaid Services, an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention's National Center for Health Statistics while providing medical expertise in epidemiology, pediatrics, allergy and immunology, and analytical support. In 2012, LCDR Quinto was commissioned in the U.S. Public Health Service and holds the rank of lieutenant commander. He completed his allergy and immunology fellowship and pediatric residency at the University of California, San Diego, earned his M.D. from the University of California, San Francisco, his M.P.H from University of California, Berkeley and his B.S. from the University of California, Los Angeles.



Sebastian Schneeweiss, MD, ScD, is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital. His research focuses on assessing the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed analytic methods to improve the accuracy of estimating causal treatment effects of new drugs using complex digital healthcare databases. His work is published in >500 articles and is used for regulatory and coverage decision-making around the globe. He is funded by NIH, PCORI, IMI, and FDA where he is also a voting consultant. He is Principal Investigator of the FDA Sentinel Innovation Center and co-leads the RCT-DUPLICATE initiative to understand when and how real-world evidence studies can reach causal conclusions.



Shirley Wang, PhD, ScM is an Associate Professor at Brigham and Women's Hospital, Harvard Medical School and Lead Epidemiologist for the Food and Drug Administration's (FDA) Sentinel Innovation Center. Her research is focused on 1) developing innovative, non-traditional analytic methods to understand the safety and effectiveness of medication use in routine clinical care as well as 2) facilitating appropriate use of complex methods for analyzing large observational healthcare data. She is currently PI on 3 NIH R01s and is also funded by FDA. Her methods work has received 3 awards from international societies. Dr. Wang co-led the 1st and 2nd joint task forces for the International Society of Pharmacoepidemiology (ISPE) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) focused on real-world

evidence for healthcare decision-making. She co-directs the REPEAT Initiative, a non-profit program with projects aimed at improving transparency, reproducibility and robustness of evidence from healthcare databases. She co-leads RCT-DUPLICATE, a series of projects designed to inform when and how real-world evidence studies can draw causal conclusions to inform regulatory or other healthcare decision-making.