Introduction to Innovation in Medical Evidence and Development Surveillance (IMEDS):
The Research Resource

Webinar
October 30, 2024 | 1:30-2:30pm (eastern)

Speakers & Panelists

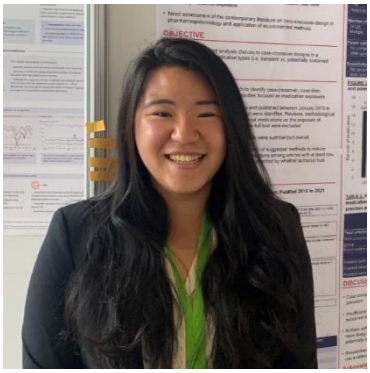
Jacqueline Corrigan-Curay, JD, MD
Principal Deputy Center Director - Center for Drug Evaluation and Research, FDA

Jacqueline Corrigan-Curay, J.D., M.D., is the Principal Deputy Center Director in FDA's Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations.

Previously, Dr. Corrigan-Curay was director of CDER's Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and as a practicing attorney in Washington, D.C.

Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical assistant professor of medicine. She has continued to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, D.C.

Claire (Hsiao-Ching) Huang, MPH, PhD
Research Scientist, Reagan-Udall Foundation for the FDA

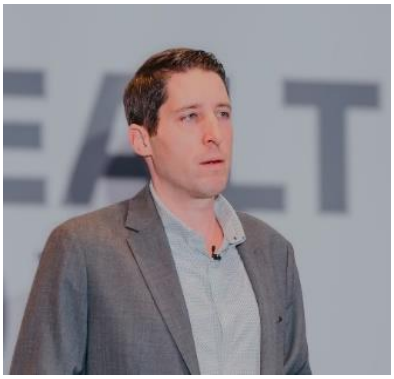


Dr. Claire (Hsiao-Ching) Huang is a Research Scientist at the Reagan-Udall Foundation for the FDA. She earned her doctoral degree in Philosophy from the University of Illinois Chicago (UIC) College of Pharmacy where she majored in Pharmacoepidemiology. Her expertise lies with epidemiology methods, real-world evidence, and patient safety.

Prior to joining the FDA Foundation, Dr. Huang worked as a summer intern at The Food and Drug Administration (FDA) where she assisted CURE-ID (drug repurposing) team with study guideline development. She also worked as a Research Fellow at Global Epidemiology of AbbVie Inc where she primarily worked on women's health projects. Before going back to school to get her PhD, Dr. Huang worked as a Statistical Analyst at Sutter Health where she conducted analyses using retrospective databases.

Dr. Huang holds a bachelor's degree in biomedical science from Kaohsiung Medical University, and a master's degree in Public Health from UIC. She is also a certified Advanced SAS programmer.

Ryan D. Kilpatrick, PhD
Vice President and Head of Global Epidemiology, AbbVie, Inc.



Ryan is currently the Vice President and Head of Global Epidemiology within AbbVie's Pharmacovigilance and Patient Safety (PPS) organization. The Global Epidemiology department generates RWE to inform the benefit-risk of our therapies, treatments, and devices. This includes design and conduct of observational post-marketing safety studies (PMSS) for regulatory decision making as well as other evidence generation to support strategic priorities and asset strategy. Ryan has over fifteen years of experience as a scientist and leader within the bio-pharmaceutical industry. Prior to AbbVie, he held roles at Amgen and GSK. He has published more than forty peer-reviewed manuscripts in clinical and pharmacoepidemiology/drug safety journals. Ryan has his PhD in Epidemiology from the University of California, Los Angeles (UCLA).

Cheryl N. McMahill-Walraven, MSW, PhD
Executive Director, CVS Healthspire Life Science Solutions

As Executive Director of the Safety Surveillance & Collaboration team in CVS Healthspire Life Science Solutions, Dr. Cheryl N. McMahill-Walraven has built up a 20-year portfolio of experience in public health surveillance (active & passive), drug safety, health insurance plan study designs, big data, linkages among governmental sources, distributed research networks, and health-care disparities/social determinates. She leads and coordinates a distributed collaborative research team that uses and evaluates Aetna's and CVS Health's real-world data in several distributed research networks, including: (1) FDA's Sentinel Initiative in the Sentinel Program and BEST program; (2) the Academy of Managed Care Pharmacy's Biologics and Biosimilars Collective Intelligence Collaborative; and (3) the Reagan-Udall Foundation's Innovation in Medical Evidence Development and Surveillance program and its COVID-19 Therapeutics and Diagnostics Evidence Accelerators. All work leverages Aetna's health insurance data and CVS Health's real-world data to monitor and evaluate U.S. health and health-care delivery.

Her Executive Director research functions include monitoring U.S. public health safety regarding FDA-approved drugs, biologics, and devices, developing study designs, data investigation, and chart validation reviews. Dr. McMahill-Walraven designs and analyzes prospective, randomized, quality initiative studies and observational descriptive analyses. She manages and coordinates disparity analyses that include multivariate logistic regressions and descriptive health- services analyses on quality metrics comparing racial and ethnic groups and self-reported primary language to advise the business on improving health-care insurance services. She also advises other departments within Aetna on research methods.

Kristin Palmsten, ScD
Senior Research Investigator, HealthPartners Institute

Dr. Palmsten is a Senior Research Investigator, Co-Director of the Pregnancy and Child Health Research Center, and Research and Scientific Mentor at HealthPartners Institute. Dr. Palmsten is a perinatal epidemiologist and pharmacoepidemiologist. She received her doctorate in Epidemiology from the Harvard T.H. Chan School of Public Health and completed a postdoctoral fellowship in the Department of Pediatrics at the University of California San Diego. Dr. Palmsten's research focuses primarily on perinatal epidemiology, pharmacoepidemiology, and assessing the risks and safety of medication use during pregnancy and lactation.

Georgia Peeples, MPH
Program Coordinator, Reagan-Udall Foundation for the FDA

Georgia Peeples serves as the Program Coordinator for the Reagan-Udall Foundation for the FDA. As a part of the IMEDS team, she provides coordination of research partnerships in epidemiology, clinical trials, and biomedical and behavioral research. Prior to joining the Foundation, Ms. Peeples was a Senior Clinical Trial Coordinator at the Medical University of South Carolina, where she managed the implementation and coordination of oncology clinical trials.

Ms. Peeples earned a master's degree in Public Health from the Medical University of South Carolina with a concentration in Health Behavior and Health Promotion and a bachelor's degree in Public Health from the College of Charleston.

Darren Toh, ScD
DPM Endowed Professor, Department of Population Medicine
Harvard Medical School, Harvard Pilgrim Health Care Institute

Darren Toh, ScD is DPM Endowed Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is a pharmacoepidemiologist with an interest in the comparative safety and effectiveness research of medical products. His research focuses on 1) assessing the risks and benefits of medical products using real-world data collected as part of routine healthcare delivery, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks.

Dr. Toh is Principal Investigator of the Operations Center of the FDA-funded Sentinel System, a congressionally mandated national medical product safety surveillance system. He is also Principal Investigator of projects funded by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes Research Institute, and the Food and Drug Administration. He is a Fellow of the International Society for Pharmacoepidemiology. Dr. Toh received his doctoral degree in Epidemiology from the Harvard School of Public Health.

Susan C. Winckler, RPh, Esq.
Chief Executive Officer, Reagan-Udall Foundation for the FDA

Susan C. Winckler 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 juris doctorate 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.

Carla Rodriguez-Watson, PhD, MPH
Director of Research, Reagan-Udall Foundation for the FDA

Carla Rodriguez-Watson, PhD, MPH is the Director of Research for the Reagan-Udall Foundation for the FDA. An epidemiologist by training, she brings her extensive experience in real-world data for public health surveillance and health outcomes research to develop initiatives focused on improving and leveraging real-world data, methods, settings, to advance the safety and effectiveness of medical products, particularly for populations with high unmet need. This work takes many forms: multi-stakeholder convenings, regulatory science, education programs to develop the next generation of scientists, and ultimately research and analysis with the Innovation in Medical Evidence and Surveillance (IMEDS) Network – a distributed network of 9 health systems (125 M covered lives) leveraging the FDA Sentinel Initiative tools and framework - where regulatory science tools and learnings can be implemented.

Carla earned her PhD in Epidemiology from the University of Washington School of Public Health, her MPH from Columbia University Mailman School of Public Health, and her BA from Rutgers University.