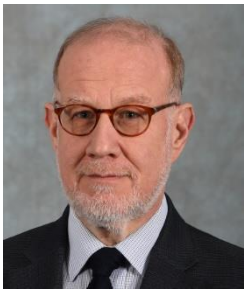
Duke Margolis-FDA Workshop: Advancing Premarket Safety Analytics

Virtual Public Workshop

September 14, 2022, 12:00–5:00 p.m. ET

Speaker Biographies

FDA Opening Remarks



Peter Stein is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters.

A nationally recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late-stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience.

Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.

Vaishali Popat is an Associate Director for Biomedical Informatics in the Office of New Drugs, FDA. Dr. Popat is the founding director of the Biomedical Informatics team, which leads Safety Analytics initiatives in areas such as pre-market safety evaluation, data standards, and staff training on the use of new tools to make the evaluation of pre-marketing data more efficient and consistent. Dr. Popat is board certified in Internal Medicine, Endocrinology and Clinical informatics, and has extensive knowledge of regulatory review, medicine, computer science and information technology. She graduated with the Master of Public Health degree from the Johns Hopkins University and completed a fellowship in Endocrinology from the National Institutes of Health.

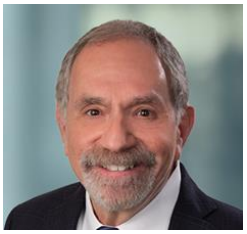
Dr. Popat has received two Dr. Frances Kelsey Drug Safety Excellence awards, the Center Director's Special Citation and Recognition award for her work in Safety Analytics and the Commissioner's special citation and recognition for her work in Clinical Informatics. She enjoys teaching and mentoring new reviewers in the use of new technologies and review tools. Dr. Popat's work focuses on Safety Analytics, data visualizations, and developing recommendations to ensure that CDER effectively responds to the rapidly evolving drug development landscape.

Overview of FDA Medical Queries

Scott Proestel is a Senior Medical Officer on the Biomedical Informatics and Regulatory Review Science Team at the US Food and Drug Administration's Center for Drug Evaluation and Research. He obtained his medical degree from Columbia University in 1992 and completed his internal medicine training at Johns Hopkins Hospital in 1995. He is board certified in internal medicine and clinical informatics, and has previously conducted and supervised pre-market reviews of new drug applications as a Medical Officer and Team Leader at FDA, overseen HIV clinical trial conduct as an Office Director at the US National Institutes of Health, and supervised post-market safety surveillance as a Division Director at FDA. His most recent informatics research assessed the use of artificial intelligence to evaluate spontaneous safety reports submitted to the FDA Adverse Event Reporting System and Vaccine Adverse Event Reporting System.

Eric Brodsky is the Associate Director of the Labeling Policy Team in the Office of New Drugs in the Center for Drug Evaluation and Research at the FDA. Dr. Brodsky oversees OND's implementation of the U.S. Prescribing Information (USPI) regulations and guidances to help promote consistency in labeling practices across CDER; develops labeling resources for CDER staff and industry; provides oversight of labeling quality; provides labeling review training; and assists review teams in review and development of the USPI. Prior to joining the FDA, Dr. Brodsky practiced as an internist with a focus in primary care and hospital medicine in the Washington D.C. area. He received his medical degree from Tufts University School of Medicine, completed an internal medicine residency program at the University of Massachusetts Medical Center, and is board certified in Internal Medicine.

Stakeholder Perspectives Exploring Premarket Adverse Event Grouping



Ellis Unger focuses on the development of promising new drug and biological therapies and shepherding them through the FDA approval process. A board-certified cardiologist with more than 24 years of experience at FDA and 14 years of experience in translational research at the National Institutes of Health (NIH), Dr. Unger provides strong scientific and regulatory insight. Dr. Unger advises biotech and pharmaceutical senior executives and development teams on strategic direction at critical moments during drug development, from phase 1 matters to complex phase 3 study design issues.

From early 2020 until his FDA retirement in August 2021, Dr. Unger was the Director of the Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN) in CDER's Office of New Drugs, with oversight of the reviewing divisions in those therapeutic areas. From 2012 to 2020, he was the Director of the Office of Drug Evaluation-I, which oversaw the regulation of drugs in the neurological, psychiatric, cardiovascular, and renal therapeutic areas. In his 9-year tenure as an FDA Office Director, Dr. Unger was directly involved in the regulation and approval of scores of new drugs and therapeutic biologics. Dr. Unger joined the FDA in 1997, initially as a medical officer, team leader, and subsequently branch chief in FDA's Center for Biologics Evaluation and Research (CBER).

Dr. Unger obtained his Medical degree from the University of Cincinnati College of Medicine in 1980, and was inducted into the Alpha Omega Alpha Medical Honor Society. Following his residency in Internal Medicine at the Virginia Commonwealth University, he obtained cardiology training at The Johns Hopkins Hospital in 1987.

Greg Ball served in the Navy and taught HS math and physics before earning his MS in statistics from Purdue and PhD in biostatistics from the University of Texas. His research on blinded safety monitoring procedures is being developed in collaboration with statistical and clinical scientists at several pharmaceutical companies (including AbbVie and Merck). He co-leads, with Mary Nilsson, the PHUSE Safety Analytics working group. Greg established, with Bill Wang, the ASA Biopharm Safety Monitoring working group and has been pioneering the joint DIA-ASA Interdisciplinary Safety Evaluation (DAISE) scientific working group, to advocate for aggregate safety assessments and cross-disciplinary scientific engagement.

Barbara Hendrickson, is the Immunology Therapeutic Area Head in Pharmacovigilance and Patient Safety at AbbVie. She is a subspecialist in Pediatrics and Infectious Diseases and maintains a clinical appointment at the University of Chicago. Dr. Hendrickson has 18 years of pharmaceutical industry experience. At AbbVie, she has worked with Safety Statistics on multiple initiatives related to aggregate safety assessment and internal Data Monitoring Committees. She also co-leads the Drug Information Association-American Statistical Association Aggregate Safety Assessment Planning Task Force.

Overview of the Standard Safety Tables and Figures Integrated Guide

Nhi Beasley is Associate Director for Biomedical Informatics (ADBMI) in the Office of New Drugs at the Food and Drug Administration (FDA). She is a member of the Biomedical Informatics and Regulatory Review Science team, and supports the Office of Cardiology, Hematology, Endocrinology and Nephrology. She has more than 20 years of regulatory and clinical review experience including seven years as a Clinical Pharmacologist/Pharmacometrician, and 14 years as a Clinical Reviewer at the FDA. In addition to mentoring reviewers, Dr. Beasley leads initiatives and serves on working groups aimed to advance biomedical informatics and safety analytics. She has been recognized with numerous FDA Agency awards, including two Dr. Frances Kelsey Drug Safety Excellence awards, and the Center Director's Special Citation and Recognition award for her work in safety analytics. Externally, she has worked with the Pharmaceutical Users Software Exchange (PHUSE) Standard Analysis and Displays Project Team since 2015, and she worked on the development of the Heart Failure Clinical Data Interchange Standards Consortium (CDISC) Therapeutic Area User Guide. She received her Bachelor and Doctor of Pharmacy degrees from Philadelphia College of Pharmacy and Science. She subsequently completed a residency in cardiology at the Veterans Affairs Medical Center / University of Tennessee (UT) and a cardiology fellowship focused in pharmacogenomics and heart failure at UT and University of Florida. Dr. Beasley is also a Commander in the U.S. Public Health Service. Her notable deployments include COVID-19 in 2021 and 2020, Hurricane Sandy in 2012, and Hurricane Katrina in 2005.

Veronica Pei is a board-certified emergency physician and a commissioned officer in the U.S. Public Health Service currently serving as Associate Director for Biomedical Informatics (ADBMI) for the Division of Gastroenterology (DG) and Division of Hepatology and Nutrition (DHN) in the Office of New Drugs (OND). In this role, Dr. Pei is involved in development, implementation, and support of bioinformatics initiatives within OND. She is the current FDA topic lead for ICH M11 expert working group on the Structure and Content of Clinical Protocols. She served as a member of the Standard Tables and Figures working group and

as the co-lead for the DILI and Hypersensitivity Follow-on Guide. More recently, Dr. Pei served as project co-lead for development of Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of NASH guidance.

Prior to joining the FDA, Dr. Pei was a practicing emergency physician with interests in medical education and global emergency medical system development. After completing her B.Sc. in Biological Sciences at the University of Toronto and her M.D. at McMaster University, Dr. Pei received a Master of Education in Health Professional Education from the University of Toronto in Canada. She subsequently completed residency training in Emergency Medicine at the Hospital of the University of Pennsylvania and fellowship training in International Emergency Medicine and received a Master of Public Health in International Health Policy and Programs at the George Washington University.

Mat Soukup received his Ph.D. in Biostatistics from the University of Virginia in 2004. Mat joined FDA/CDER in September 2004 as a statistical reviewer supporting the review of dermatology and dental product submissions. In 2010, he joined the Division of Biometrics VII as Team Lead and now serves as Deputy Division Director. In these roles, Mat contributes and promotes appropriate statistical methodologies for the quantitative assessment of safety covering a broad spectrum of topics such as meta-analysis, causal inference, signal detection, statistical graphics, and design of safety outcome trials.

Examining Strategies for Premarket Adverse Event Analysis

Mary Nilsson received a MS degree in statistics from Iowa State University in 1989. She has been employed at Eli Lilly and Company since 1989 and is currently a researcher in the Safety Analytics group. She consults with molecule teams on safety analysis planning for Phase 2-3 studies and integrated submission documents. Her primary interests include analyses of adverse event data, analyses of laboratory data, statistical analysis plans, and collection and analysis of suicide-related events. Additionally, she co-leads the PHUSE Safety Analytics Working Group involved with creating cross-functional education and cross-industry recommendations for standard safety analyses and displays.

Bess LeRoy is the Head of Standards Development at CDISC. Bess has been a CDISC team member since 2011 and is leading the development of the CDISC Analysis Results Standard. Bess has over 20 years' experience working in public health research and has held positions at the Framingham Heart Study, the Rotterdam Study, the Arizona Cancer Center, and the Critical Path Institute. Bess has a BS from the University of Michigan, an MPH from Boston University School of Public Health, and is a doctoral candidate at Johns Hopkins Bloomberg School of Public Health.

Jeremy Wildfire is a Data Scientist at Gilead and is focused on creating modern tools that improve the analysis pipeline for clinical trials. Jeremy has served as the technical lead for the Interactive Safety Graphics (ISG) sub-team of the ASA Biopharm-DIA Safety Working Group since 2018. The working group is an interdisciplinary effort that seeks to provide a clinical safety workflow for monitoring during clinical development in an open-source model. The ISG team created a workflow to monitor hepatoxicity using the safetyGraphics R package and a well-documented clinical workflow based on the safety clinician's monitoring practice. The working group has recently expanded its focus to include additional safety domains including adverse events, QT and nephrotoxicity.

Duke-Margolis Moderators

Marianne Hamilton Lopez is the Senior Research Director of Biomedical Innovation, an adjunct associate professor, and core faculty at the Duke-Margolis Center for Health Policy in Washington, DC. She leads the strategic design and direction of the Center's Biomedical Innovation portfolio, with a focus on medical products development and regulation, real world evidence, infectious disease preparedness, and payment, pricing, and coverage of drugs and medical devices. She also oversees the Value for Medical Products Consortium and partners with Duke University faculty, scholars, and external health experts to advance this work. Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a senior program officer with the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System and led the Consortium's Science and Technology portfolio and Clinical Effectiveness Research Innovation and the Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community Advisor for the United States Cochrane Center; and the Federal Women's Program Manager and American Indian/Alaska Native Employment.