Pediatric Developmental Safety Assessment and New Approach Methodologies

A Virtual Workshop sponsored by the U.S. Food and Drug Administration and the Triangle Center of Excellence in Regulatory Science and Innovation

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Workshop Planning Committee

Dr. **Gilbert Burckart** is Associate Director for Pediatrics in the Office of Clinical Pharmacology at the U.S. Food and Drug Administration. He received his B.S. in Pharmacy from the University of Pittsburgh, Pharm.D. from the University of Kentucky, and completed a pediatric residency at the UK Medical Center and Norton Children's Hospital. Dr. Burckart previously held faculty positions at the State University of New York at Buffalo, University of Tennessee, and University of Pittsburgh, where he was Professor of Pharmacy, Pediatrics, and Surgery, and Director of Research for the Division of Cardiothoracic Surgery. His research focused on drug therapy in organ transplantation and was supported by NIH grants in liver and lung transplantation. He later served as Chairman of the Department of Pharmacy and Director of the Clinical Pharmacogenomics Laboratory at the University of Southern California. A former President of both the American College of Clinical Pharmacy and the American College of Clinical Pharmacology, Dr. Burckart received the Sumner J. Yaffe Lifetime Achievement Award in 2014. At FDA since 2008, he leads pediatric clinical pharmacology programs and mentors students, fellows, and faculty nationwide.

Althea Cuff, MS is a Senior Regulatory Project Manager in the Executive Programs and Project Management (EPPM) staff in the Office of Clinical Pharmacology (OCP) at the Food and Drug Administration. Prior to joining FDA in 2007, Althea served as a Medical Technologist/Laboratory Manager at various hospitals in the Washington DC, area, to include Howard University, Children's National Medical Center, Holy Cross Hospital, and the Walter Reed National Medical Center. She received her Bachelor of Science in Clinical Laboratory Science from Howard University and a Master of Science degree in Bioscience/Regulatory Affairs from Johns Hopkins University. Since joining at FDA, Althea has served in a number of regulatory positions in the Office of New Drugs Quality Assessment, Office of Surveillance and in the Office of New Drugs.

Christin Daniels, MA works in the Eshelman Innovation division within the UNC Eshelman School of Pharmacy as Executive Director of the Triangle Center of Excellence in Regulatory Science and Innovation (CERSI), an FDA-funded consortium uniting UNC-Chapel Hill, Duke University, North Carolina Central University, North Carolina State University, and the Burroughs Wellcome Fund. With over 26 years of executive leadership in biomedical research and innovation, she provides strategic, operational, programmatic and financial direction to advance science and accelerate translation for public health benefit. Daniels previously served as Associate Chief Operating Officer at the Duke Human Vaccine Institute, Assistant Dean for Research Development at the Duke University School of Nursing, Senior Director of Research & Innovation at the UNC Gillings School of Global Public Health and Director of Research Administration at the Shriners Hospital for Children in Lexington, Kentucky. Daniels earned her terminal MA in Experimental Psychology from Radford University and her BS in Psychology from the University of Mary Washington. She has helped secure $1.6B in research grants over her career, co-authored 15 peer-reviewed articles, presented 60+ talks/posters at national meetings and is the recipient of four awards.

Neha Mehta, M.S. is a Regulatory Health Project Manager in the Office of Clinical Pharmacology within FDA CDER. Mehta graduated from the University of Maryland with a BA in Anthropology and the University of Maryland, Baltimore with an MS in Pharmacometrics. She currently is a Project Manager within the Office of Clinical Pharmacology at the FDA.

Paul B. Watkins, MD is a clinically trained hepatologist and leading investigator in drug metabolism and hepatotoxicity, recognized for his research on why safe and effective drugs can sometimes cause liver injury. His work spans basic laboratory science and patient-based clinical studies, advancing understanding of drug-induced liver injury (DILI) mechanisms and genetic susceptibility. Dr. Watkins currently co-chairs the Steering Committee and chairs the Genetics Committee of the U.S. Drug-Induced Liver Injury Network (DILIN), funded by the National Institutes of Health, and serves as Principal Investigator of the Triangle Center of Excellence in Regulatory Science and Innovation (CERSI), funded by the U.S. Food and Drug Administration. A graduate of Cornell University (B.A. in Physical Chemistry) and Cornell Medical College (M.D.), Dr. Watkins has received numerous honors, including the Agilent Therapeutic Frontiers Award (2013), Rawls-Palmer Award (2015), and the Distinguished Scientist Award (2023) from the American College of Toxicology.