FDA: Bringing Clinical Research to Patients Webinar

November 8, 2023

Hosted by the FDA Office of Women's Health (OWH), in collaboration with the Center for Drug Evaluation and Research (CDER) Office of Medical Policy (OMP), this is a free public webinar to discuss the new strategies currently available for bringing clinical research to all patients, including women.

WEBINAR SPEAKERS

Leonard Sacks, MBBCh
Associate Director
Clinical Methodologies, Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Dr. Sacks received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa, and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics.

Dr. Sacks holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.

Ryan Robinson, MD
Physician
Clinical Methodologies, Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Dr. Robinson is a physician in clinical methodologies in the Office of Medical Policy in the Center for Drug Evaluation and Research. He received his M.D. from Southern Illinois University School of Medicine in 2002 and subsequently completed a residency in Emergency Medicine and a fellowship in Primary Care Sports Medicine. Dr. Robinson has practiced clinically in Emergency Medicine and Sports Medicine, worked as a Medical Officer in the Center for Devices and Radiological Health, and served as a Global Clinical Development Lead in industry prior to joining the Office of Medical Policy in 2021. He has experience in drug and device development including clinical trial design and analysis, protocol development, and clinical operations as well as drug and device regulation. In his current position, Dr. Robinson supports policy efforts to modernize clinical trials including those related to decentralization and the use of digital health technologies in clinical trials.

Mili Duggal, PhD, MPH
Staff Fellow
Clinical Methodologies, Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Dr. Duggal is a maternal and child health specialist who joined the CURE ID team in 2016. She has a PhD in global maternal and child health from the University of Maryland School of Public Health, and an MPH in global health from Tulane University. Dr. Duggal leads the Pregnancy and Neonatal sub-projects of the program and is excited to see the CURE ID platform expand to address these issues of substantial public health need. She also provides critical support to many other aspects of the program.

U.S. FOOD & DRUG ADMINISTRATION

Office of Women's Health

www.fda.gov/womens