

Good Clinical Practice: Considerations for Trials with Pragmatic or Decentralized Features

September 12 & 13
7:30 AM - 9:30 AM US Eastern

Speaker Bios

Discussion Moderator

M. Khair ElZarrad PhD, MPH (Day 1 & 2)

Director, Office of Medical Policy

Center for Drug Evaluation and Research, U.S. Food & Drug Administration



Khair ElZarrad is the Director of the Office of Medical Policy (OMP) at FDA's Center for Drug Evaluation and Research (CDER), where he leads the development, coordination, and implementation of medical policy programs and strategic initiatives. He currently leads multiple projects focused on exploring the potential utility of real-world evidence, innovative clinical trial designs, and the integration of technological advances in pharmaceutical development. Dr. ElZarrad is the rapporteur for the International Council for Harmonisation's ongoing work to revise the international Good Clinical Practice Guideline (ICH-E6).

Prior to joining the FDA, he served as Acting Director of the Clinical and Healthcare Research Policy Division with the Office of Science Policy at the National Institutes of Health (NIH). At NIH he worked on policies related to human subject protections; the oversight of clinical research; and enhancing quality assurance programs at pharmaceutical development and production facilities. He earned a doctoral degree in medical sciences with a focus on cancer metastases from the University of South Alabama, as well as a master's degree in public health from the Johns Hopkins Bloomberg School of Public Health.

Panelists

Otavio Berwanger, MD, PhD (Day 2)

Executive Director, The George Institute for Global Health

Chair in Clinical Trials, Imperial College London



Otavio Berwanger is Executive Director for The George Institute for Global Health, UK and Chair in Public Health at Imperial College London. In his capacity as Executive Director he leads the Institute's work in partnership with Imperial College London, with its core focus on health systems science, multimorbidity, women's health, large-scale clinical trials and planetary health. He will also build on his personal research interests in exploring innovative clinical trial models, as well as the conduct of efficient implementation science studies.

Prior to joining The George Institute, UK, Otavio was Director of the Academic Research Organization (ARO) of the Albert Einstein Israelite Hospital in São Paulo, Brazil. An esteemed cardiologist and clinical trialist, Otavio has extensive research and managerial experience and has led large-scale, randomized clinical trials nationally and internationally across countries including Brazil, Australia, New Zealand, Canada, China, Chile, Argentina, Peru and Colombia. Trials led by Otavio have been published in high-impact journals such as the New England Journal of Medicine, Lancet, JAMA and BMJ.

Noelle Cocoros, DSc, MPH (Day 2)

Principal Research Scientist, Harvard Pilgrim Health Care Institute

Principal Associate in Population Medicine, Harvard Medical School



Dr. Noelle Cocoros is a Principal Research Scientist in the Harvard Pilgrim Health Care Institute and a Principal Associate in the Department of Population Medicine at Harvard Medical School. She has a background in infectious disease epidemiology, pharmacoepidemiology, and public health surveillance. Her expertise in uses of electronic health data for research, evaluation, and

surveillance ranges from pandemic response to pragmatic trials. Dr. Cocoros is the Lead Epidemiologist at the Operations Center for the US FDA’s Sentinel System, an active post-market surveillance system for regulated medical products. Prior to joining the Institute, she was with the Massachusetts Department of Public Health for nearly eight years.

Adrian Hernandez, MD, MHS (Day 2)

Cardiologist, Vice Dean and Executive Director of Duke Clinical Research

Duke University School of Medicine



Dr. Adrian Hernandez is Executive Director, Duke Clinical Research Institute, and Vice Dean of the Duke University School of Medicine. Dr. Hernandez is a cardiologist who has research interests in improving health by accelerating clinical evidence through outcomes research, clinical trials, comparative effectiveness and health policy. He has led multiple large-scale patient-centered research programs, registries and clinical trials aimed at improving health across

multiple conditions such as NIH’s Health System Collaboratory and the PCORI-funded PCORnet®, the National Patient-Centered Clinical Research Network and other landmark clinical trials. He has served as the steering committee chair or principal investigator on multiple studies and has authored over 800 publications. He is an elected member of the American Society for Clinical Investigation and the Association of American Physicians.

Eric Lenze, MD (Day 1)**Professor, Head of Psychiatry & Director of the Healthy Mind Lab****Washington University School of Medicine in St. Louis**

Dr. Eric Lenze is professor, Head of Psychiatry and Director of the Healthy Mind Lab at Washington University School of Medicine in St. Louis. Dr. Lenze is best-known for his research in depression, anxiety, and cognitive functioning in older adults. Among his more than 300 publications are studies published in the Journal of the American Medical Association, the New England Journal of Medicine, and the Lancet. He is also known for COVID-19 research: in 2020, he led a team that showed the drug fluvoxamine could prevent deterioration in people with initially mild symptoms. This research was widely reported in the media, including a segment on 60 Minutes. Dr. Lenze has championed digital and other remote techniques in his research. In 2014, he led a study funded by the FDA to test if generic forms of the antidepressant bupropion performed clinically similar to the brand form; utilizing then-novel smartphones, he measured daily symptoms and side effects in an innovative clinical trial format. Then, in a large NIH-funded study of lifestyle interventions for cognitive function in older adults, he utilized smartphones and tablets to remotely measure participants' symptoms, sleep, and adherence to the study. Another recent study funded by PCORI allowed for fully-remote participation in a test of antidepressant strategies for treatment-resistant depression in older adults. More recently, both his COVID trials and a new, ongoing study of fluvoxamine for the treatment of long COVID have included fully-remote participants, in which screening, consent, intervention, and outcome assessment have all been conducted remotely.

Craig Lipset, MPH (Day 1)**Co-Chair, Decentralized Trials & Research Alliance****Adjunct Professor, Rutgers University****Vice President, Foundation for Sarcoidosis****Managing Partner, Clinical Innovation Partners**

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Lipset is Co-Chair for the Decentralized Trials & Research Alliance and Vice President of the Foundation for Sarcoidosis. He is Adjunct Assistant Professor in Health Informatics at Rutgers University and serves on the Advisory Council for HL7 Project Vulcan and External Stakeholder Board for IMI Trials at

Home.

Lipset was previously the Head of Clinical Innovation and Venture Partner at Pfizer, and on the founding management teams for two successful startup ventures.

Kenichi Nakamura, MD, PhD, MBA (Day 1)

**Director, Department of International Clinical Development & Chief Management Officer,
Clinical Research Support Office**

National Cancer Center Hospital



Dr. Kenichi Nakamura is the Director of the Department of International Clinical Development, National Cancer Center Hospital. He graduated from Kyoto University in 1999. He had training as a general surgeon for seven years and then moved to National Cancer Center to engage in the operation and management of Japan Clinical Oncology Group, the largest cancer clinical trial group in Japan. Since 2015, he has developed the department for supporting investigator-initiated registrational trials at National Cancer Center Hospital, one of the

largest academic research organizations in Japan. In 2020, he launched the ATLAS project to develop a multi-national clinical trial network among Asian countries. He also serves as an academic representative in the ICH E6 (R3) working group.

FDA Foundation

Amar Bhat, PhD

Chief Operating Officer

Reagan-Udall Foundation for the FDA



Amar Bhat, PhD, is the Chief Operating Officer of the Reagan-Udall Foundation for the FDA, a non-profit organization created by Congress to advance the mission of the U.S. Food and Drug Administration. In this role, he works closely with the CEO to provide strategic direction, leadership, and oversight for the Foundation's programs and initiatives intended to foster advances in regulatory science and help FDA modernize product development and accelerate innovation.

Dr. Bhat joined the Foundation in May 2018 as the Director of Business Planning and Programs, with a portfolio that focused on new initiatives, program development and strategic planning. From April 2019 to May 2020, he served as Interim Executive Director. Prior to joining the Foundation, Dr. Bhat held a variety of executive positions in health and science policy, including Vice President of Open Health Systems Laboratory, President and Co-Founder of TwoFour Insight Group, and Assistant Vice President of the Pharmaceutical Research and Manufacturers of America (PhRMA). Dr. Bhat is a recognized speaker on global health and pharmaceutical policy.

Lea Ann Browning-McNee, MS
Director of Communications and Stakeholder Engagement
Reagan-Udall Foundation for the FDA



Lea Ann Browning-McNee translates complex science, research and policy into practical, meaningful stories relevant to the Reagan-Udall Foundation's stakeholders.

Before joining the Foundation, Lea Ann helped launch BrainFutures, a national nonprofit focused on promoting breakthroughs in brain health and was instrumental in bringing Mental Health First Aid to the United States during her tenure at the National Council for Behavioral Health. She also served in senior leadership positions at the Mental Health Association of Maryland and the National Mental Health Association. She holds a bachelor's degree in Communications and a master's degree in Writing from Towson University.