Center for Drug Evaluation and Research (CDER)/Center for Biologics Evaluation and Research (CBER)

Public Workshop: Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice

FDA Great Room, Building 31
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002
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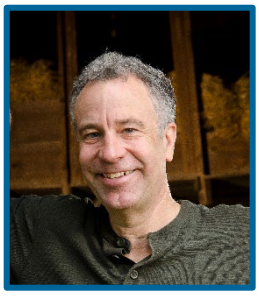
Biographies

Frank Bretz is a Distinguished Quantitative Research Scientist at Novartis. He has supported the methodological development in various areas of drug development, including adaptive designs, dose finding, estimands, multiple endpoint analyses. Frank was a member of the ICH E9(R1) Expert Working Group on 'Estimands and sensitivity analysis in clinical trials' and currently serves on the ICH E20 Expert Working Group on 'Adaptive clinical trials.' He is an Adjunct Professor at the Hannover Medical School (Germany) and the Medical University Vienna (Austria). Frank is a Fellow of the American Statistical Association.



Dean Follmann graduated from Carnegie Mellon University with a PhD in statistics in 1985. Since 2002 he has served as Chief of the Biostatistics Research Branch at the National Institute of Allergy and Infectious Diseases (NIAID). He has authored more than 250 peer-reviewed research articles, received the Department of Health and Human Services Secretary's Award for Distinguished Service, and is an elected Fellow of the American Statistical Association. He serves on committees and advisory boards for the US Food and Drug Administration, the National Institutes of Health, philanthropic organizations, and academic departments. Current research interests focus on statistical methods related to vaccinology, immune correlate analyses, and causality. https://www.niaid.nih.gov/about/brb-staff-follmann

Frank Harrell received his PhD in Biostatistics from UNC in 1979. Since 2003 he has been Professor of Biostatistics, Vanderbilt University School of Medicine, and was the department chairman from 2003-2017. He is Expert Biostatistics Advisor to FDA CDER and was Expert Biostatistics Advisor for the Office of Biostatistics for FDA CDER from 2016-2020. He is Associate Editor of Statistics in Medicine. He is a Fellow of the American Statistical Association and winner of the Association's WJ Dixon Award for Excellence in Statistical Consulting for 2014. His specialties are development of accurate prognostic and diagnostic models, model validation, clinical trials, observational clinical research, cardiovascular research, technology evaluation, pharmaceutical safety, Bayesian methods, quantifying predictive accuracy, missing data imputation, and statistical graphics and reporting.

Rebecca Hubbard is Professor of Biostatistics and Vice Chair for Faculty Professional Development in the Department of Biostatistics, Epidemiology & Informatics at the University of Pennsylvania. Her research addresses challenges arising in research using electronic health records (EHR) including missing data, measurement error and algorithmic fairness. This work has been applied to research on cancer epidemiology including EHR-based studies of cancer screening, treatment and survivorship. She is an elected Fellow of the American Statistical Association, a statistical editor for the New England Journal of Medicine and has published over 200 peer-reviewed papers.

J. Jack Lee is Professor of Biostatistics and Kennedy Foundation Chair in Cancer Research. His areas of expertise include design and analysis of cancer clinical trials, Bayesian adaptive designs, statistical computation / simulations / graphics, drug combination studies, and biomarker identification and validation. He is an elected Fellow of the American Statistical Association, the Society for Clinical Trials, and the American Association for the Advancement of Science. He has more than 500 publications in statistical and medical journals. He has co-authored two books, entitled: "Bayesian Adaptive Methods for Clinical Trials" and "Model-Assisted Bayesian Designs for Dose Finding and Optimization: Methods and Applications."

Roger J. Lewis is a Senior Physician in the Los Angeles County Department of Health Services, Professor of Emergency Medicine at the David Geffen School of Medicine at UCLA, and a Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in innovative clinical trial design. Dr. Lewis is the senior statistical editor for JAMA and editor of the JAMA series entitled "JAMA Guides to Statistics and Methods." His expertise centers on adaptive and Bayesian clinical trials, including platform trials; general clinical research methodology; data and safety monitoring boards, and the oversight of clinical trials. Dr. Lewis was elected to membership in the National Academy of Medicine in 2009.

Dr. Lewis is the former Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center. He has previously served as a member of the Blood Products Advisory Committee of the US Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services, and on multiple consensus committees of the National Academy of Medicine. He has chaired data and safety monitoring boards (DSMBs) for numerous federally funded, industry-sponsored, and multinational clinical trials. Dr. Lewis has served as a content reviewer for many other peer reviewed journals. He has authored or coauthored over 270 original research publications, reviews, editorials, and chapters.

Herbert (Herb) Pang is an Expert Statistical Scientist in PD Data Sciences, Genentech/Roche. Herb obtained his MBA from Hong Kong University of Science and Technology, PhD in Biostatistics from Yale, and BA in Mathematics and Computer Science from Oxford. He was formerly a tenured Associate Professor at the University of Hong Kong (HKU). His research interests include RWE for drug development, machine learning, biomarker discovery, and the design and analysis of clinical trials.

He was a key member of the Genentech team involved in the FDA's CID pilot program submission involving external control in DLBCL. Herb is currently a PI on an FDA grant under the NIH U01 mechanism on RWE. He is also a member of the ASA Biopharmaceutical section RWE working group and Chair of the ASA Biopharmaceutical section Distance Learning committee. Herb remains as an Honorary Associate Professor at HKU and is also an adjunct faculty member in the Department of Biostatistics and Bioinformatics at Duke.

Karen Price received her PhD in Statistics from Baylor University in 2001 and joined Lilly at that time. She is Vice President, Statistical Innovation Center-Advanced Analytics, a team focused on enabling innovative design and analysis of clinical trials. Her research interests include innovative clinical trials, quantitative decision making, and Bayesian methods. She previously led the DIA Bayesian Scientific Working Group, and currently serves as advisor. Karen is a Fellow of the American Statistical Association.

Stephen Ruberg received a bachelor's degree in Mathematics from Thomas More College, an MS in Statistics from Miami of Ohio, and a PhD in Biostatistics from the University of Cincinnati. Dr. Ruberg was in the pharma industry for 38 years where he worked in all phases of drug development and commercialization – from R&D to Business Analytics. He retired from Lilly at the end of 2017. In his last 10 years at Lilly, he formed the Advanced Analytics Hub for which he was the Scientific Leader and ultimately the Distinguished Research Fellow. Dr. Ruberg is presently the Founder and President of Analytix Thinking, LLC and an Adjunct Professor of Statistics at Purdue University.

He has been a Fellow of the American Statistical Association (ASA) since 1994, was given the Career Achievement Award by Quantitative Scientists in the Pharmaceutical Industry and was elected a Fellow of International Statistics Institute.

Dr. Ruberg has served in many leadership roles related to the pharmaceutical industry and the statistical profession. He was on the Expert Working Group for ICH-E9 Statistical Principles for Clinical Trials and a co-author of that Guidance. He also served on an Advisory Committee on the use of electronic medical records to the Secretary of Health and Human Services during the Bush administration.

Dr. Ruberg's current research interests include estimands, subgroup identification, Bayesian methods for clinical drug development, and digital medicine.