U.S. FOOD & DRUG ADMINISTRATION

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

Public Meeting : Promoting the Use of Complex Innovative Designs in Clinical Trials
FDA Great Room, Building 31, Room 1503
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002
March 20, 2018

Biographies

Deborah Ashby is Interim Head of the School of Public Health at Imperial College London where she holds the Chair in Medical Statistics and Clinical Trials, and was Founding Co-Director of Imperial Clinical Trials Unit. She is a Chartered Statistician and her research interests are in clinical trials, risk-benefit decision making for medicines, and the utility of Bayesian approaches in these areas. She led the benefit-risk workstream of the IMI-funded PROTECT project, bringing together academic, pharmaceutical, regulatory and patient expertise to determine best practice, and innovate on both underpinning methods and communication of the benefits and risks of medicines.

She chairs the HTA Commissioning Board, and is Deputy Chair of the HTA Programme for the National Institute for Health Research, and is Chair of the Population Research Committee for Cancer Research UK. She has sat on the UK Commission on Human Medicines and acts as adviser to the European Medicines Agency. Deborah was awarded the OBE for services to medicine in 2009, appointed an NIHR Senior Investigator in 2010, elected a Fellow of the Academy of Medical Sciences in 2012 and is currently President-Elect of the Royal Statistical Society.

Julie Beitz has had a 23-year career at FDA involving both pre- and post-approval regulatory activities. Since 2006, she has served as the Director, Office of Drug Evaluation III. In this capacity, she oversees the review activities of the Division of Gastroenterology and Inborn Errors of Metabolism, the review division responsible for advising manufacturers on the development and approvability of new drugs and biologic products intended to treat rare metabolic disorders.

Dr. Beitz came to FDA in 1994 as a medical officer in the Division of Oncology Drug Products, and served as medical team leader and later as the Acting Deputy Director for the division. In 2000, she was named the Director of the Division of Drug Risk Evaluation in the Office of Surveillance and Epidemiology, a division responsible for identifying and assessing safety signals associated with drug use in the postmarket setting. In 2003, she joined the Office of Drug Evaluation III as the Deputy Office Director and was later named Office Director. Since November 2007 she has served on several working groups involved in the implementation of the new regulatory authorities provided for under the FDA Amendments Act of 2007 (FDAAA). In addition, she serves as the CDER liaison for the Office of Women's Health, and is a member of CDER's Medical Policy Council, and Drug Development Tools Committee. Prior to working at FDA, Dr. Beitz was Assistant Professor of Medicine at Brown Medical School, and a practicing medical oncologist/hematologist at the Roger Williams Medical Center in Providence, RI. She is a graduate of Barnard College and Columbia University's College of Physicians and Surgeons.

Scott Berry is President and a Senior Statistical Scientist at Berry Consultants, LLC. He earned his PhD in statistics from Carnegie Mellon University and was an Assistant Professor at Texas A&M University before co-founding Berry Consultants in 2000. He is adjunct faculty in the Department of Biostatistics at the University of Kansas Medical Center. Dr. Berry was elected as a Fellow of the American Statistical Association in 2013.

Since 2000, he has been involved in the design of hundreds of Bayesian adaptive clinical trials of pharmaceuticals and medical devices and has become an opinion leader in the field of Bayesian adaptive clinical trials. Some of these trials have been groundbreaking trial designs, setting new standards for innova-

tion and flexibility in trial design. These include the trials supporting the first fully Bayesian approval by CDER of the United States FDA (Pravastatin-Aspirin combination) and the statistical design for Time Magazine's #2 Medical Breakthrough of 2007 (Veridex's GeneSearch BLN Assay), and an adaptive phase II/III seamless trial for Trulicity® leading to FDA approval in September 2014. Recently he has been involved in the design of the IMI Funded platform trial for prevention of Alzheimer's disease (EPAD), the DIAN-TU platform trial in dominantly inherited Alzheimer's, and the EU funded platform trial for the treatment of severe community acquired pneumonia (REMAP-CAP) in a preparedness setting (PREPARE).

Frank Bretz joined Novartis in 2004, where he is currently Global Head of the Statistical Methodology and Consulting group. Frank has a keen interest in advancing practices of drug development. He has supported the methodological development in various areas of pharmaceutical statistics, including dose finding, multiple comparisons, and adaptive designs. Frank is currently holding Adjunct/Guest professorial positions at the Hannover Medical School (Germany), Shanghai University of Finance and Economics (P.R. China), Medical University of Vienna (Austria) and Osaka University (Japan). Among other professional services, he is a co-founding editor of the Springer Series in Pharmaceutical Statistics and the editor-in-chief of Statistics in Biopharmaceutical Research. He has authored or co-authored more than 150 articles in peer-reviewed journals and four books. Frank is a Novartis Distinguished Scientist, a recipient of the Susanne-Dahms-Medal from the German Region of the International Biometric Society and a Fellow of the American Statistical Association.

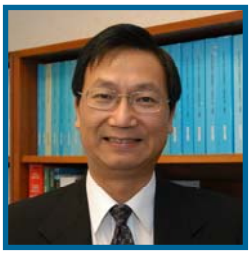
Aloka Chakravarty is the Acting Director of the Office of Biostatistics in CDER, FDA. Dr. Chakravarty joined CDER in 1992 and brings to her current position considerable experience in CDER. She is an internationally recognized thought leader in multi-regional clinical trials, safety evaluation, surrogate markers and biomarkers in drug development and has presented and published widely on it. Her research interests include MRCTs, surrogate endpoint methodology, biomarkers, interim analysis, meta-analysis, Bayesian methodology, safety evaluation and statistical computing. Dr. Chakravarty served as an Adjunct Faculty in Department of Statistics, Foundation for Advanced Education in the Sciences, National Institutes of Health.

Dr. Chakravarty has received numerous awards, including the FDA Award of Merit in 2008 and Dr. Frances O. Kelsey Drug Safety Excellence Award in 2012. Aloka received her Ph.D. in Statistics from Temple University, and M.Stat from Indian Statistical Institute. Dr. Chakravarty is a Fellow of the American Statistical Association and an Associate Editor of Statistics in Biomedical Research.

Ivan S.F. Chan has 20+ years of experience in pharmaceutical industry. He is Vice President, Pipeline Statistics and Programing, Data & Statistical Sciences, at AbbVie Inc. In this capacity, he leads the statistics and programing groups supporting discovery, biomarker development, clinical development and global medical affairs for all therapeutic areas. Prior to joining AbbVie, Ivan was Executive Director of Biostatistics at Merck Research Laboratories.

Ivan earned a M.S. in Statistics from The Chinese University of Hong Kong and a Ph.D. in Biostatistics from University of Minnesota. Professionally, Ivan serves as Executive Director of the International Society for Biopharmaceutical Statistics (ISBS) and as an External Advisor to the University of Hong Kong. Also, he is an Associate Editor (AE) for Statistics in Biosciences, Statistics in Biopharmaceutical Research, and Journal of Biopharmaceutical Statistics. He was the 2012 President of the International Chinese Statistical Association. He has 80+ publications in statistical and clinical journals.

Ivan was inducted as a Fellow of the American Statistical Association (ASA) and a Fellow of the Society for Clinical Trials (SCT) in 2011.



Shein-Chung Chow is currently an Associate Director at Office of Biostatistics, CDER/FDA. Prior to joining FDA, Dr. Chow was a Professor at the Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC. He was also a special government employee (SGE) appointed by the FDA as an Advisory Committee member and consultant to the FDA. Prior to that, Dr. Chow also held various positions in the pharmaceutical industry such as Vice President, Biostatistics, Data Management, and Medical Writing at Millennium Pharmaceuticals, Inc., Cambridge, MA; Executive Director, Statistics and Clinical Programming at Covance, Inc.,

Director and Department Head at Bristol-Myers Squibb Company, Plainsboro, NJ. Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Editor-in-Chief of the Biostatistics Book Series at Chapman and Hall/ CRC Press of Taylor & Francis Group. He was elected Fellow of the American Statistical Association and an elected member of the ISI (International Statistical Institute). Dr. Chow is the author or co-author of 300 methodology papers and 28 books including Design and Analysis of Bioavailability and Bioequivalence Studies, Sample Size Calculations in Clinical Research, Adaptive Design Methods in Clinical Trials, and Biosimilars: Design and Analysis of Follow-on Biologics.

Scott S. Emerson Scott S. Emerson, M.D., Ph.D. is Professor Emeritus of Biostatistics at the University of Washington. He holds an undergraduate degree in physics, an M.D., and a Master's degree in computer science (all from the University of Virginia) and a Ph.D. in Biostatistics (University of Washington). He held faculty positions at the University of Florida and the University of Arizona prior to joining the Department of Biostatistics at the University of Washington, where he directed the graduate program in Biostatistics and collaborated on clinical trials in a variety of diseases including cardiovascular disease and cancer. A major focus of his statistical research has been in the use of sequential methods, both frequentist and Bayesian, in the monitoring and reporting of clinical trial results, especially in the setting of time to event analyses. Dr. Emerson served on the National Academies of Science panel on the prevention and treatment of missing data in randomized clinical trials and serves on a number of government and industry sponsored Data Safety Monitoring Boards (DSMBs). Computer programs that he developed for sequential clinical trials now form the backbone of S+SeqTrial, an S-PLUS module for group sequential trial design that has been ported to R as RCTdesign.

Steven Goodman is Associate Dean for Clinical and Translational Research, Professor of Medicine and of Epidemiology, and Chief of the Division of Epidemiology at the Stanford University School of Medicine. He directs the Stanford CTSA TL1 and KL2 research training programs, and is the co-founder and co-director of METRICS (Meta-Research Innovation Center at Stanford), a center dedicated to scientifically studying and improving the validity of published biomedical research. He is a senior statistical editor of Annals of Internal Medicine, serves as Vice-Chair of the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI) and is Scientific Advisor to the Medical Advisory Panel of the national Blue Cross-Blue Shield technology assessment program. He was the editor of Clinical Trials: The Journal of the Society for Clinical Trials from 2004-2013. Before joining Stanford in 2011, for two decades he was a member of and then director of the Division of Biostatistics and Bioinformatics in the Johns Hopkins Kimmel Cancer Center. He has long written about inferential and Bayesian approaches in clinical research, and co-organized the 2004 FDA conference “Can Bayesian Approaches to Studying New Treatments Improve Regulatory Decision Making?" He was awarded the 2016 Spinoza Chair from the University of Amsterdam for his work in inference.

Frank E Harrell Jr 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 Statistical Advisor for the Office of Biostatistics for FDA CDER. He is Associate Editor of Statistics in Medicine, a member of the Scientific Advisory Board for Science Translational Medicine, a member of the Faculty of 1000 Medicine, and a member of the policy advisory board for the Journal of Clinical Epidemiology. 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. He was the 2017 Visionary Speaker, Clinical Studies Coordinating Center, University of North Carolina Department of Biostatistics. 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.

Telba Irony is Deputy Director of the Office of Biostatistics and Epidemiology at CBER. She joined FDA to implement the use of Bayesian statistics for the regulation of medical devices, and led the Decision Analysis initiative at CDRH including Bayesian statistics, benefit-risk determinations, and the science of patient input.

Telba received the 2014 FDA Excellence in Analytical Science Award for spearheading innovative regulatory science studies culminating in the release of novel guidance documents, supporting com-

plex policy decision making and changing the submission review paradigm. She has a PhD from Berkeley, is a fellow of the American Statistical Association, and an elected member of the International Statistical Institute.

Laura Lee Johnson is an acting division director and the Patient Focused Drug Develop liaison for the Office of Biostatistics in CDER at FDA. She specializes in design, logistics including data collection and transmission, implementation, and analysis of research studies ranging from clinical outcome assessment (COA) qualification to safety and randomized studies of all sizes. She works across CDER and other parts of FDA on patient focused drug development initiatives. Prior to working at the FDA she spent over a decade at the U.S. National Institutes of Health working on and overseeing clinical research and research support programs including the CTSAs, PROMIS, and the NIH Collaboratory. She has co-authored several articles and book chapters across a variety of disciplines and served on NIH and PCORI review and methods panels. Among her many activities Dr. Johnson serves on the FDA-NIH Interagency Clinical Outcome Assessments Working Group, the IMI PREFER Scientific Advisory Board, and co-directs the NIH Principles and Practice of Clinical Research course.

Stefanie Kraus is a Regulatory Counsel in the Office of Regulatory Policy within CDER. After practicing pharmaceutical antitrust litigation for ten years at Proskauer Rose, LLP, a large international law firm, Stefanie earned her MPH at the Harvard School of Public Health where she focused on pharmaceutical development and policy. She joined CDER in 2016 and brings a wealth of legal, policy, and scientific experience to her role in developing regulatory policy. Stefanie focuses on policy and legal and regulatory issues relating to drug development, clinical trials, real world evidence, and serves on CDER's steering committee for complex innovative trial designs, real world evidence, and model-informed drug development.

Lisa LaVange is Professor and Associate Chair of the Department of Biostatistics in the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. In her role as associate chair, she coordinates development of the data science curriculum at the Gillings School. She is also director of the department's Collaborative Studies Coordinating Center (CSCC), overseeing faculty, staff, and students involved in large-scale clinical trials and epidemiological studies coordinated by the center. Currently, she is Principal Investigator for the Adolescent Medicine Trials in HIV/AIDS Interventions Network Coordinating Center at the CSCC.

From 2011 to 2017, Dr. LaVange was director of the Office of Biostatistics in the United States Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER). There, she oversaw more than 200 statisticians and other staff members involved in the development and application of statistical methodology for drug regulation. She was a leader in developing and assessing the effectiveness and appropriateness of innovative statistical methods intended to accelerate the process from drug discovery to clinical trials to FDA approval and patients' benefit. Prior to her government and academic experience, Dr. LaVange spent 16 years in non-profit research and 10 years in the pharmaceutical industry.

Dr. LaVange is an elected fellow of the American Statistical Association (ASA) and is the 2018 ASA President. She is also former president of the Eastern North American Region of the International Biometric Society (ENAR-IBS) and former IBS Board member. She is instructor for a graduate course in statistical leadership and a guest lecturer in the clinical trials course, both at UNC.

J. Jack Lee is Professor of Biostatistics, Kenedy Foundation Chair in Cancer Research, and Associate Vice President in Quantitative Sciences at the University of Texas MD Anderson Cancer Center. His areas of interest include design and analysis of clinical trials, Bayesian adaptive designs, statistical computation/graphics, biomarkers and genomics research, etc. Dr. Lee has actively participated in cancer clinical trials and basic science studies and has extensive experience in analyzing biomarker data collected from translational studies. In addition, Dr. Lee has been active in teaching/mentoring graduate students, residents, and fellows. He is an adjunct professor at the University of Texas School of Public Health and is a full member of the University of Texas Graduate School of Biomedical Sciences.

Dr. Lee earned his D.D.S. from the National Taiwan University in 1982; M.S. and Ph.D. in Biostatistics from the University of California at Los Angeles in 1984 and 1989. Dr. Lee is a Statistical Editor for *Journal of the National Cancer*

Institute and *Cancer Prevention Research*. He is an elected Fellow of the American Statistical Association and the Society for Clinical Trials. He has more than 400 publications in statistical and medical journals and is a co-author of a book entitled: "Bayesian Adaptive Methods for Clinical Trials".

Gregory Levin is the Acting Deputy Director of the Division of Biometrics II in the Office of Biostatistics at the FDA's Center for Drug Evaluation and Research. Greg joined FDA after receiving a PhD in biostatistics from the University of Washington in 2012. At FDA, Greg has provided statistical support for reviews of applications for pulmonary, allergy, rheumatology, metabolism, and endocrinology products. He is involved in the planning and teaching of several training courses at FDA and participates on many committees and working groups, including groups charged with drafting regulatory guidance. He is also an Associate Editor for Statistics in Biopharmaceutical Research. His research interests include missing data, adaptive design, biosimilars, and making real-world inference from clinical trials.

Roger J. Lewis received his PhD in Biophysics and MD from Stanford University. He is a Professor at the David Geffen School of Medicine at UCLA and Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center. Dr. Lewis's expertise centers on adaptive and Bayesian clinical trials, including platform trials; translational, clinical, health services and outcomes research; interim data analysis; data monitoring committees; and informed consent in emergency research studies.

In 2009, Dr. Lewis was elected to membership in the National Academy of Medicine (formerly the Institute of Medicine). He is a Past President of the Society for Academic Emergency Medicine (SAEM), currently a member of the Board of Directors for the Society for Clinical Trials, and the Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in adaptive clinical trials.

Dr. Lewis has served as a grant reviewer for the Agency for Healthcare Research and Quality (AHRQ), the Canadian Institutes of Health Research (CIHR), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute of France, the National Institutes of Health (NIH), the Patient Centered Outcomes Research Institute (PCORI) and foundations. He is a member of the Blood Products Advisory Committee of the US Food and Drug Administration, Center for Biologics Evaluation and Research (CBER) and has served as a member of the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services and as the chair of data and safety monitoring boards (DSMB) for both federally-funded and industry-sponsored clinical trials, including international trials. He is a research methodology reviewer for *JAMA* and an editor of the *JAMA* series entitled "JAMA Guides to Statistics and Methods." He has served as a content reviewer for many other peer reviewed journals. He has authored or coauthored over 240 original research publications, reviews, editorials, and chapters.

Gracie Lieberman is a Biostatistician with 30+ years of experience in oncology clinical trials. Gracie is a Director of Regulatory Policy at Genentech and one of her focus areas is utilization of Real World Data in regulatory decision-making.

During the first 8 years of her professional career, Gracie worked at the Institute of Tuberculosis and Pulmonary Diseases in Warsaw, Poland, where she assisted surgeons and oncologists collect, analyze and interpret data from lung cancer trials. In this setting, she had the privilege to participate in the daily rounds, meet patients and observe their struggles. For the past 24 years at Genentech, Gracie has gained experience in all phases of drug development, from pre-IND to post-marketing, drug/diagnostic co-development, and collection/evaluation of Patient Reported Outcomes (PROs). Gracie served on review and oversight committees, advising and guiding molecule development teams and participated in select strategic initiatives such as 2NME Development Considerations. She also led a Biostatistics Initiative on Drug/Diagnostic Co-Development. Gracie has a Master's Degree in Biostatistics from the University of North Carolina at Chapel Hill.

Olga V. Marchenko is a Head of Clinical Statistics in Pulmonology, Anti-Infectives, Ophthalmology, and Women's Health therapeutic areas at Bayer. Prior to joining Bayer, Dr. Marchenko was Vice President and Head of Advisory Analytics at QuintilesIMS. She has 20+ years of experience in design and analysis of clinical trials. Dr. Marchenko received her PhD in Statistics from the University of Michigan, Ann Arbor. She holds a Master's degree in Statistics from the Ohio State University and a Master's degree in Science Mathematics from the Belarusian State University (Minsk,

Belarus). Dr. Marchenko's research interests include adaptive design methodology and implementation, drug safety methods and analyses, and statistical methods and models in cancer research. She published and presented on novel designs in clinical trials, and was a guest co-editor of special issues for Therapeutic Innovation & Regulatory Science, Journal of Biopharmaceutical Statistics, and Statistics in Biopharmaceutical Research. She is an Associate Editor of Journal of Biopharmaceutical Statistics and a Fellow of American Statistical Association.

Cyrus R. Mehta is President and co-founder of Cytel Corporation and Adjunct Professor of Biostatistics, Harvard University. Cytel (www.cytel.com) is a leading provider of software, clinical services and strategic consulting on the design, interim monitoring and implementation of adaptive clinical trials, with offices in the United States, Europe and India. Dr. Mehta consults extensively with the biopharmaceutical industry on group sequential and adaptive design, offers workshops on these topics, and serves on data monitoring and steering committees for trials in many therapeutic areas. He has over 110 publications in leading statistics and medical journals. He is a past co-winner of the George W. Snedecor Award from the American Statistical Association, is a Fellow of the American Statistical Association, and an elected member of the International Statistical Institute. He was named Mosteller Statistician of the Year by the Massachusetts Chapter of the American Statistical Association in 2000, and Outstanding Zoroastrian Entrepreneur by the World Zoroastrian Chamber of Commerce in 2002. He has received the Lifetime Achievement Award from the International Indian Statistical Association (2015) and the Distinguished Alumi Award from the Indian Institute of Technology, Bombay (2016).

William J. Meurer is currently an Associate Professor of Emergency Medicine and Neurology at the University of Michigan Health System. He works to improve the care of patients with acute neurological disease both through his work on the acute stroke team and as a researcher. His work in the field focuses on the design of clinical trials with adaptive and flexible components. In addition, he is a principal investigator of the National Institutes of Neurological Disorders and Stroke (NINDS) Clinical Trials Methodology Course (http://neurotrials.training) and a co-investigator in the clinical coordinating center of the Strategies to Innovate Emergency Clinical Care Trials (SIREN) network - also funded by NIH). He is principal investigator of NIH funded trials that include an ED based text messaging intervention for hypertension and a cluster randomized trial to improve the care of patients with acute dizziness. He was a co-investigator on the Adaptive Designs Accelerating Promising Treatments into Trials (ADAPT-IT) project, as part of the FDA Advancing Regulatory Science initiative with NIH.

Thomas Permutt is Associate Director for Statistical Science and Policy, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research. His training in decision theory and causal inference have enabled him to take a radical approach to innovation in clinical trial design and analysis over twenty-five years as a reviewer. Dr. Permutt is FDA topic leader for the revision of the guideline on Statistical Principles for Clinical Trials of the International Council for Harmonization, chair of the CDER Statistical Policy Council, and a member of the Medical Policy and Program Review Council.

Dionne L Price is the acting Deputy Director of the Office of Biostatistics in the Office of Translational Sciences, Center for Drug Evaluation and Research, FDA. During her FDA career, Dr. Price has played an active role in the development and application of methodology used in the regulation of anti-infective, anti-viral, ophthalmology, transplant, analgesia, anesthesia, and addiction drug products. Dr. Price holds a MS in Biostatistics from the University of North Carolina at Chapel Hill and a PhD in Biostatistics from Emory University. Dr. Price is an active member of the International Biometric Society and the American Statistical Association.

Karen Lynn Price received her Ph.D. in Statistics from Baylor University in 2001, and joined Eli Lilly and Company at that time. She is currently Senior Research Advisor at Eli Lilly and Company where she leads the Statistical Innovation Center, a team that focuses on innovative design and analysis of clinical trials. In 2012, Karen formed the DIA Bayesian Scientific Working Group and currently serves as past-chair. This group includes members in Industry, Regulatory, and Academia. The group's mission is to ensure that Bayesian methods are well-understood, accepted, and broadly utilized throughout medical product development. Her research interests include Bayesian meta-analysis, Bayesian methods for safety signal detection and evaluation, and Bayesian design and analysis of clinical trials. In 2016, Karen was elected a Fellow of the American Statistical Association.

John Scott is Acting Director of the Division of Biostatistics in the FDA's Center for Biologics Evaluation and Research, where he has also served as Deputy Director and as a statistical reviewer for blood products and for cellular, tissue and gene therapies. Prior to joining the FDA in 2008, he worked in psychiatric clinical trials at the University of Pittsburgh Medical Center and did neuroimaging research with the Neurostatistics Laboratory at McClean Hospital, Harvard Medical School. His research interests include Bayesian and adaptive clinical trial design and analysis, drug and vaccine safety, data and text mining, and benefit-risk assessment. He holds a Ph.D. in Biostatistics from the University of Pittsburgh and an M.A. in Mathematics from Washington University in St. Louis, and is an editor of the journal, Pharmaceutical Statistics.

Rajeshwari Sridhara is the Division Director of Division of Biometrics V, Office of Biostatistics which supports Office of Hematology Oncology Products at the Center for Drug Evaluation and Research (CDER). She joined the Food and Drug Administration (FDA) in 1999. Dr. Sridhara has contributed in the understanding and addressing the statistical issues that are unique to the oncology disease area such as evaluation and analysis of time to disease progression. Her research interests also include evaluation of surrogate markers and design of clinical trials. She has organized, chaired and given invited presentations at several workshops. She has worked on many regulatory guidance documents across multiple disciplines. She has extensively published in refereed journals and presented at national and international conferences. She is an elected fellow of the American Statistical Association. Prior to joining FDA, Dr. Sridhara was a project statistician for the AIDS vaccine evaluation group at EMMES Corporation, and she was an assistant professor at the University of Maryland Cancer Center.

Joseph G. Toerner received his undergraduate degree from the University of Dayton, his MD degree from Case Western Reserve University and his MPH degree from Johns Hopkins School of Public Health. He completed training in Internal Medicine at CWRU University Hospitals of Cleveland/Cleveland Veterans Administration Medical Center and completed fellowship training in Infectious Diseases at Georgetown University Medical Center. After spending four years as a clinician-educator and as assistant professor of medicine at University of California, San Diego, he joined FDA in 1998 as a medical reviewer. During his time at FDA he has held medical reviewer, team leader, and deputy director positions in review division in CDER and CBER. He is currently Deputy Director for Safety in the Division of Anti-Infective Products.

Z. John Zhong is a Senior Director of Biostatistics at Biogen where he plays a critical role in the use of innovative statistics and trial designs across several therapeutic areas, including rare diseases. Dr. Zhong has actively participated in company-specific interactions with regulators as well as multi-company dialogues with regulators on the topic of innovative clinical trial design. He is a member of BIO Innovative Clinical Trials Taskforce and contributed to the development of a series of recommendations for consideration regarding application timelines, communication on acceptance/rejection into the Complex Innovative Design Pilot Program, and disclosure of information. He is also a member of PhRMA Clinical Development Work Group and contributed to the US landscape assessment of complex innovative clinical trial designs. In addition, Dr. Zhong is a member of DIA Bayesian Scientific Working Group. He received his PhD in Mathematical Statistics from the university of Maryland at College Park. He has more than 20 years of experience in the industry and medical research; and published over 50 manuscripts in peer reviewed medical and statistical journals.