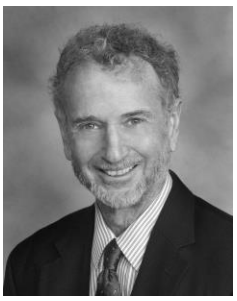
ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

**Expert Workshop:**
**Pioneering Statistical Approaches to Accelerate Drug Development through Adaptive Trial Designs**
The Brookings Institution • Washington, DC
Thursday, March 27, 2014

**Biographies**



**Donald A. Berry, PhD,** is a professor in the Department of Biostatistics of the University of Texas MD Anderson Cancer Center. He was founding Chair of this department in 1999 and founding Head of the Division of Quantitative Sciences, including the Department of Bioinformatics and Computational Biology, in 2006. Dr. Berry received a PhD in statistics from Yale University, and previously served on the faculties of the University of Minnesota and Duke University. He held endowed faculty positions at Duke University and at MD Anderson. Since 1990 he has served as a faculty statistician on the Breast Cancer Committee of the Cancer and Leukemia Group B, a national oncology group, now part of The Alliance. He has designed and supervised the conduct of many large U.S. intergroup trials in breast cancer. A principal focus of his research is the use of biomarkers in cancer and other diseases for learning which patients benefit from which therapies, based on genomics and phenotype. He designed and is a co-principal investigator of I-SPY 2, a Bayesian adaptive platform clinical trial in high-risk early breast cancer whose goal is matching experimental therapies with patient subsets defined by tumor molecular characteristics. Since 1997 he has served on the PDQ Screening and Prevention Board of the National Cancer Institute for which he received the National Institutes of Health Award of Merit in 2010. Through Berry Consultants, LLC he has designed many innovative clinical trials for pharmaceutical and medical device companies and for National Institutes of Health (NIH) cooperative groups. Dr. Berry is the author of several books on statistical methodology and over 300 published articles, including first-authored articles in the major medical journals. Dr. Berry has been the principal investigator for numerous research grants from the NIH and the National Science Foundation. He is a fellow of the American Statistical Association and the Institute of Mathematical Statistics.

**Marc Buyse, ScD,** holds a ScD in biostatistics from the Harvard School of Public Health. He worked at the EORTC in Brussels and at the Dana-Farber Cancer Institute in Boston. He is the founder of the International Drug Development Institute (IDDI) and of CluePoints, two biostatistical service organizations based in the U.S. and Europe. Marc currently lives in the Bay Area. His research interests include clinical trial design, validation of biomarkers and surrogate endpoints, statistical methods in oncology, statistical detection of errors, and meta-analysis.

**Gregory Daniel, PhD, MPH, RPh,** is a fellow in Economic Studies and managing director for evidence development and innovation in the Engelberg Center for Health Care Reform at the Brookings Institution. In this position, Dr. Daniel oversees and provides strategic direction regarding the Center's evidence development and biomedical innovation portfolio, including medical product safety surveillance, regulatory science and U.S. Food and Drug Administration (FDA) policy issues, comparative effectiveness research, and other biomedical innovation policies. Dr. Daniel was previously Vice President, Government and Academic Research at HealthCore (subsidiary of WellPoint, Inc.) where he led a division responsible for providing research services in the areas of pharmacoepidemiology; drug, vaccine, and biologic safety evaluations; comparative effectiveness research; and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist

and holds a PhD in pharmaceutical economics, policy, and outcomes research with a minor in epidemiology from the University of Arizona. He also holds an MPH specializing in biostatistics, a master's in pharmaceutical administration, and a BS in pharmacy, all from The Ohio State University.

**Brenda L. Gaydos, PhD,** received her PhD in mathematical statistics from Pennsylvania State University. She has been employed by Eli Lilly and Company since 1997. She currently leads the cross-disciplinary Science Driven Adaptive Program team. This group is charged with corporate transformational efforts in the areas of clinical development scenario planning and decision making through the use of modeling and simulation, novel trial designs and analyses to increase clinical development efficiencies. She is an adjunct associate professor of biostatistics at the Indiana School of Medicine, and a fellow of the American Statistical Association (ASA). Dr. Gaydos is active in the pharmaceutical community. She has held elected and appointed positions in ASA, has co-chaired the PhRMA working group on Adaptive Designs (2005-2009), chaired the PhRMA response to the FDA Draft Guidance on Adaptive Designs (2010), and chaired the DIA Adaptive Design Scientific Working Group (2010 to Q3 2013). She is an elected member of Quantitative Sciences in the Pharmaceutical Industry (QSPI), which serves the interests of senior leadership of statistical, data management and statistical programming organizations in the biotechnology and pharmaceutical industry. In addition she has contributed to the advancement of innovation through publications and education. She has given well over 50 invited lectures including conference presentations, webinars, workshops, and training courses on statistical methods.

**Robert J. Gray, PhD,** received his PhD in statistics from Oregon State University in 1982 and has since been affiliated with the Dana-Farber Cancer Institute and Harvard University. He has been a member of the faculty at Harvard University since 1984 and a tenured professor of biostatistics since 2003. Dr. Gray became a clinical trials statistician with the Eastern Cooperative Oncology Group (ECOG) in 1982, working primarily with its Breast Cancer Committee. He became Associate Director of the ECOG Statistical Center in 1998 and was appointed the ECOG Group Statistician in 2000. He now leads the Biostatistics and Data Management Center of the ECOG-ACRIN Cancer Research Group jointly with Constantine Gatsonis. Under his leadership at the Statistical Center, ECOG conceived and completed numerous landmark cancer clinical studies that have changed the standards of care in cancer treatment. One notable example is the Trial Assigning IndividuaLized Options for Treatment (TAILORx), a first-of-its-kind therapeutic study that is investigating the use of the OncotypeDX® breast cancer assay to evaluate the effect of chemotherapy in women with a midrange risk of their cancer returning, as determined by the Oncotype DX Recurrence Score®. Dr. Gray has served as Chair of the Committee of Group Statisticians for the National Cancer Institute (NCI) since 2003 and is a member of the NCI Breast Cancer Steering Committee and the Breast Cancer Intergroup Correlative Science Committee.

**Michael R. Kosorok, PhD,** is the W. R. Kenan, Jr. Distinguished Professor and Chair of Biostatistics, Professor of Statistics and Operations Research, Member of the Lineberger Comprehensive Cancer Center, and Director of the Biostatistics Service of the Translational and Clinical Sciences Institute, University of North Carolina at Chapel Hill. His areas of expertise include clinical trials, survival analysis, dynamic treatment regimes, semiparametric inference, and empirical processes, and he has written a major text on the theoretical foundations of these and related areas in biostatistics (Kosorok, 2008). He is an honorary fellow of both the American Statistical Association and the Institute of Mathematical Statistics and is the contact principal investigator on a program project from the National Cancer Institute entitled "Statistical Methods for Cancer Clinical Trials" which is a joint endeavor between Duke University, North Carolina State University, and the University of North Carolina.

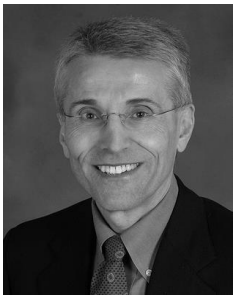
**Lisa LaVange, PhD,** is Director of the Office of Biostatistics in the Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA). As Director, she oversees approximately 170 statistical reviewers and staff members involved in the development and application of statistical methodology for drug regulation. She is a member of the PDUFA V steering committee and serves on the CDER Antibacterial Drug Development Task Force. Prior to joining the FDA, Dr. LaVange was a professor and Director of the Collaborative Studies Coordinating Center (CSCC) in the Department of Biostatistics, Gillings School of Global Public Health at the University of North Carolina at Chapel Hill, where she served as principal investigator of the coordinating centers for several large-scale multi-center clinical trials, epidemiology studies, and patient registries. Before joining academia, Dr. LaVange spent ten years in the pharmaceutical industry and 16 years in non-profit research. She is a fellow of the American Statistical Association, served as President of the Eastern North American Region of the International Biometric Society (IBS, 2007), and currently serves on the IBS Executive Board. She is co-editor of the Journal of Pharmaceutical Statistics and editor-in-chief of the ASA-SIAM book series.

**Olga Marchenko, PhD,** is a vice president and Head of the Center for Statistics in Drug Development at Quintiles. Prior to joining Quintiles, Dr. Marchenko' positions included Global Head of Data Services Therapeutic Consulting and Director of Biostatistics in North America at i3 Statprobe. She also worked at Pfizer, The Ohio State University, and Belarusian State University. Dr. Marchenko's research interests include adaptive design methodology and implementation, drug safety methods and analyses, and statistical methods and biological models in cancer research. Olga 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. Dr. Marchenko is a co-chair of a working group on Safety Analysis under ASA Biopharmaceutical Section, a co-chair of industry cross-coordination committee under DIA Statistical Community, and a co-chair of Oncology Adaptive Program working group under DIA ADSWG. Dr. Marchenko has numerous publications and presentations on novel designs in clinical trials, and was a guest co-editor of the special issue of Therapeutic Innovation and Regulatory Science on Advances in Clinical Trial Statistics (January, 2014).

**Mark McClellan, MD, PhD,** is a senior fellow and director of the Initiative on Value and Innovation in Health Care at the Brookings Institution. Within Brookings, his work focuses on promoting quality and value in patient centered health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of FDA, where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University.

**Cyrus R. Mehta, PhD,** is President and co-founder of Cytel Corporation and an adjunct professor of biostatistics at Harvard University. Cytel is a leading provider of software and services for the design, interim monitoring and implementation of adaptive clinical trials. 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 led the development of the StatXact, LogXact and East software packages that are widely used in the biopharmaceutical industry and at academic research centers. He publishes his methodological research in leading statistics journals and is a past co-winner of the George W. Snedecor Award from the American

Statistical Association. He 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.



**Richard Pazdur, MD,** is presently Director of the Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research at FDA. This Office was formed in 2005 to consolidate the review of drugs and therapeutic biologics for the diagnosis, treatment, and prevention of cancer as well as the review of drugs and therapeutic biologics for hematologic diseases and for medical imaging. Dr. Pazdur's position facilitates coordination of oncology activities across all FDA Centers and ensures an ongoing outreach and collaboration between FDA, the National Cancer Institute, and other cancer-related organizations within and outside of the government. Dr. Pazdur was the Director of the Division of Oncology Drug Products from September 1999 to May 2005. Prior to joining the FDA, Dr. Pazdur was a professor of medicine at The University of Texas MD Anderson Cancer Center in Houston, Texas and was on the faculty of the MD Anderson Cancer Center from 1988 to 1999. During his tenure at MD Anderson, Dr. Pazdur held administrative positions of Assistant Vice President for Academic Affairs, Associate Director of Clinical Trials Administration (Division of Medicine), and Director of Educational Programs (Division of Medicine). Previously, Dr. Pazdur was on the faculty of Wayne State University, Detroit, Michigan from 1982 to 1988. Dr. Pazdur's main research interests are in clinical trial design and drug development of anti-cancer agents in advanced colorectal cancer. He has performed numerous phase I, II, III, and adjuvant therapy trials in this disease. Dr. Pazdur has published over 400 articles, book chapters and abstracts. He received his MD from Loyola Stritch School of Medicine, and completed his clinical training at Rush-Presbyterian St. Luke's Medical Center and the University of Chicago Hospitals and Clinics.

**Rajeshwari Sridhara, PhD,** is the Division Director of Division of Biometrics V, Office of Biostatistics with 27 statisticians supporting Office of Hematology Oncology Products, and Office of Drug Evaluation IV (Medical Imaging Products) at the Center for Drug Evaluation and Research. She joined FDA in 1999. Dr. Sridhara routinely presents the regulatory policies and scientific philosophy of the Office at national and international professional meetings. 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 in co-ordination with DIA, NCI, ASCO, ASA and PhRMA. She has worked on regulatory guidance documents across multiple disciplines, such as guidances on clinical trial endpoints for the approval of oncology drugs and biologics, adaptive designs, and enrichment designs. She has reviewed many high profile drug applications and has made several presentations at the oncology drug advisory committee meetings. She has extensively published in refereed journals and presented at national and international conferences. Prior to joining FDA, Dr. Sridhara was a project statistician for the AIDS vaccine evaluation group at EMMES Corporation for two years, and she was an assistant professor at the University of Maryland Cancer Center for six years. She is a member of American Statistical Association and American Society of Clinical Oncology.