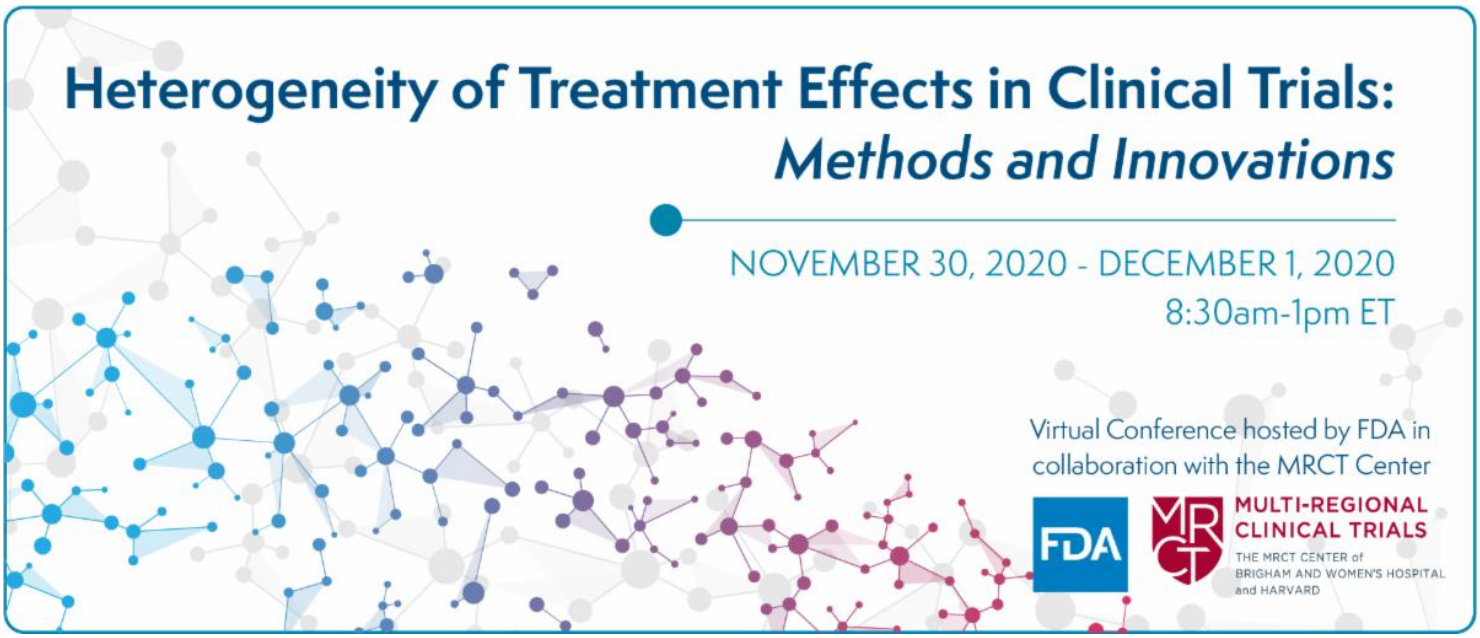
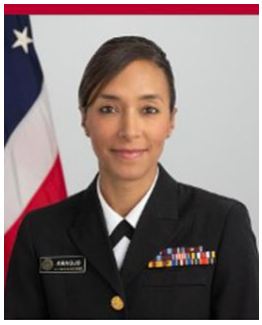


2020 BIO BOOKLET

Invited Speakers and Moderators

Barbara E. Bierer, MD is the Faculty Director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), a Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics and the Law Program of the Harvard clinical and translational sciences center. Previously she served as senior vice president, research at the Brigham and Women's Hospital for 11 years and was the institutional official for human subjects and animal research, for biosafety and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH.



RADM Richardae Araojo serves as the Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity at the U.S. Food and Drug Administration (FDA). In this role, RADM Araojo provides leadership, oversight, and direction on minority health and health disparity matters for the Agency. RADM Araojo previously served as the Director of the Office of Medical Policy Initiatives in FDA's Center for Drug Evaluation and Research (CDER), where she led a variety of broad-based medical and clinical policy initiatives to improve the science and efficiency of clinical trials and enhance professional and patient labeling. RADM Araojo joined FDA in 2003, where she held several positions in CDER. RADM Araojo received her Doctor of Pharmacy Degree from Virginia Commonwealth University, completed a Pharmacy Practice Residency at University of Maryland, and earned a Master's degree in Pharmacy Regulation and Policy from the University of Florida.

Sylva Collins, PhD joined the US Food and Drug Administration's Office of Biostatistics in the Office of Translational Sciences of the Center for Drug Evaluation and Research on August 19, 2019. She brings more than 30 years of drug development experience and biostatistics leadership to her position. Prior to joining the FDA, Collins was vice president of biometrics at ACADIA Pharmaceuticals, based in San Diego, where she led all aspects of statistical design and analysis of clinical trials, as well as statistical programming and clinical data management. She has emphasized standardization and automation to accelerate clinical development. She pioneered the large-scale deployment of electronic data capture at multiple companies, including Bayer and Novartis. She implemented standardization of biometrics systems and processes for large pharma organizations to allow near simultaneous regulatory submissions globally. She has experience leading large global biometrics organizations and has contributed to dozens of successful regulatory submissions in multiple jurisdictions.Collins earned her bachelor's degree in mathematics from the American University

of Beirut, master's and doctoral degrees in statistics from Boston University, and later a master's degree in computer science from New York University.

Robert M. Califf, MD,MACC is the Head of Clinical Policy and Strategy for Verily and Google Health. Prior to this Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

David H. Strauss, MD is a Senior Advisor for the MRCT Center. He is a psychiatrist with nearly 30 years of experience in assessment, pharmacologic treatment, and psychotherapy with individuals with anxiety, mood, and psychotic disorders. Prior to joining the staff at Austen Riggs, Dr. Strauss was full-time faculty at Columbia University and held a series of clinical and research executive positions in the Department of Psychiatry and the NYS Psychiatric Institute, including: chief of the Schizophrenia Research Unit; clinical director; chair of the Institutional Review Board/director of human subject research; vice chairman for research, ethics and policy; and director of research operations. At Columbia Psychiatry, Dr. Strauss developed and taught courses and seminars on research and professional ethics for faculty, trainees, and students. Dr. Strauss is currently a special lecturer at Columbia University. As a consultant to the NYS Psychiatric Institute, Dr. Strauss co-leads the Ethics Unit and serves on the steering committee of a federally funded center grant entitled, "Optimizing and Personalizing Interventions for People with Schizophrenia Across the Lifespan." As senior advisor to the Multiregional Clinical Trials Center at Brigham and Women's Hospital and Harvard, Dr. Strauss co-leads a project aimed at promoting diversity in clinical trials. Dr. Strauss is a member of the executive counsel of the board of directors of Public Responsibility in Medicine and Research, and co-chairs its Public Policy Committee. Dr. Strauss maintains a private practice of psychotherapy and psychopharmacology, and teaches, lectures, and consults widely on matters of human subjects' protections and applied research and professional ethics.

Donna R. Cryer, JD is the founder and Chief Executive Officer of the Global Liver Institute, the only patient-driven liver health nonprofit operating in the US and Europe. She has channeled her personal experience as a patient with inflammatory bowel disease and a 25-year liver transplant recipient into professional advocacy across a career in law, policy, consulting, public relations, clinical trial recruitment, and nonprofit management. For almost a decade Mrs. Cryer founded and led CryerHealth, a healthcare consulting firm providing strategic counsel to top biopharmaceutical companies, patient advocacy organizations, and emerging technology firms on patient engagement in health information technology, drug discovery, and clinical decision making. Mrs. Cryer serves on the Boards of Directors of The Innovation and Value Initiative (IVI), the Sibley Memorial Hospital/Johns Hopkins Medicine, the Executive Committee for the Clinical Trials Transformation Initiative and the Executive Advisory Committee for Tivity Health (NASDAQ: TVTY). She is a patient representative to the U.S. Food and Drug Administration.

Danielle M. Campbell, MPH is a member of the faculty with the Charles R. Drew University of Medicine and Science in the Department of Preventive and Social Medicine and Research Analyst at the University of California, Los Angeles. Danielle is a socio-behavioral scientist, public health strategist, and experienced research project director who integrates implementation science, biomedical and biobehavioral sciences in HIV treatment, prevention and cure research. She has close to 10 years of experience in infectious disease-related work, including the clinical and social sciences of HIV cure-related research, prevention and treatment, and recently SARS-CoV-2. The focus of Danielle's work has been examining the influence of structural systems and paradigms of power on the production of health inequities among racial/ethnic and sex/gender minority populations living with and affected by HIV/ AIDS and other marginalized populations with an emphasis on women and girls. Danielle is a community organizer for HIV/ AIDS and sexual and reproductive health, rights, and justice awareness policies and campaigns. She has conducted studies in biomedical HIV prevention, CURE, and the intersections of sexual health and HIV risk. She dedicates her energy to serving as a member of a community scientific subcommittee for a global HIV/ AIDS research network, Chair of the American Public Health Association HIV/ AIDS Section, and as a volunteer HIV tester/ counselor aboard a mobile testing unit, and as an educator and promoter of positive sexual health awareness.

Janet Wittes, PhD founded Statistics Collaborative, Inc. (SCI) in 1990. She is a Fellow of the American Statistical Association, the Society for Clinical Trials (SCT), and the American Association for the Advancement of Science, and an elected member of the International Statistical Institute. For the International Biometric Society, she was Treasurer from 1987 to 1990 and President of the Eastern North American Region in 1995. For SCT, she was a member of the Board of Directors from 1990 to 1998 and President in 2001. Dr. Wittes is a member of many advisory committees, including a large number of Data Monitoring Committees (DMCs) for randomized clinical trials sponsored by industry or government. She chairs the DMCs for several large multi-center trials sponsored by the National Institutes of Health (NIH). She is a former member of the Food and Drug Administration (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee (2014–2018) and the Circulatory System Devices Panel (1999–2003) and has been a member of several ad hoc FDA Advisory Panels.

Christopher Granger, MD is a Professor of Medicine in the Division of Cardiology at Duke University and Director of the Cardiac Care Unit for the Duke University Medical Center. Dr. Granger is a Fellow of the American College of Cardiology, the American Heart Association, and of the European Society of Cardiology. He is Associate Editor of the *American Heart Journal* and serves on the editorial board of the *Journal of the American College of Cardiology.* He is a cardiology section author for *Current Medical Diagnosis and Treatment*. He serves on the publication oversight committee of the American Heart Association and he is chairman of the Advisory Working Group of the American Heart Association Mission: Lifeline program. He is a member of the 2011 ACC/AHA STEMI Guidelines Committee. He has served on FDA advisory committees on an *ad hoc* basis. He is on the Board of External Experts of the National Heart, Lung and Blood Institute (NHLBI). Dr. Granger's primary research interest is in the conduct and methodology of large randomized clinical trials in heart disease; he has co-authored more than 500 peer-reviewed manuscripts. He currently serves on a number of clinical trial steering committees and data safety monitoring committees. He has coordinated the Duke Clinical Research Institutes' activities in many clinical trials evaluating acute MI reperfusion and antithrombotic strategies in acute coronary syndromes and in atrial fibrillation.

Ellis F. Unger, MD is a cardiologist and Director of the Office of Cardiology, Hematology, Endocrinology, and Nephrology, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. FDA. His Office oversees the regulation of cardiovascular, renal, hematological, diabetes, lipid, and general endocrine drugs. After completing his cardiology training at Johns Hopkins in 1987, Dr. Unger led a translational research program on promotion of angiogenesis in the Cardiology Branch, NHLBI, NIH. In 1997, Dr. Unger came to the Center for Biologics Evaluation and Research (CBER), FDA, where he assumed progressively increasing responsibilities. After regulatory authority for therapeutic biologics was transferred from CBER to CDER in 2003, Dr. Unger joined CDER as the Deputy Director, Division of Cardiovascular and Renal Products. Dr. Unger transitioned to the Office of Drug Evaluation-I in 2009 and served as its Director from 2012-2020. With a reorganization in 2020, Dr. Unger became the director of the Office of Cardiology, Hematology, Endocrinology, and Nephrology.

Aloka Chakravarty, PhD is currently the Senior Statistical Advisor in the Office of the Commissioner, FDA for real-world data and evidence activities related to collaborations on COVID-19 and others. She is also working on select strategic data initiatives at FDA with the Chief Data Officer. Prior to that, she was the Deputy Director of the Office of Biostatistics in CDER, FDA. She is an internationally recognized thought leader in multi-regional clinical trials, safety evaluation, real world data and evidence, surrogate markers and biomarkers in drug development. Dr. Chakravarty served as an Adjunct Faculty in Department of Statistics, FAES, NIH and has been on Advisory Board of multiple academic institutions. Dr. Chakravarty has received numerous awards, including the FDA Award of Merit and Dr. Frances O. Kelsey Drug Safety Excellence Award. She 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.

Steve Snapinn, PhD has had a long career as a biostatistician in the pharmaceutical industry, including 20 years at Merck in Pennsylvania and 15 years leading the biostatistics organization at Amgen in Thousand Oaks, California. He is currently an independent consultant at Seattle-Quilcene Biostatistics LLC and living in Seattle. During his career he led the biostatistical efforts for more than a dozen successful pharmaceutical products in multiple therapeutic area. He has over 100 publications in the statistical and medical literature, has been honored fellow of the American Statistical Association, and has served as editor of the journal Statistics in Biopharmaceutical Research.

Scott Evans, PhD is a Professor and Founding Chair of the Department of Biostatistics Bioinformatics and the Director of the George Washington Biostatistics Center. Professor Evans interests include the design, monitoring, analyses, and reporting of and education in clinical trials and diagnostic studies. He is the author of more than 100 peer-reviewed publications and three books on clinical trials including *Fundamentals for New Clinical Trialists*. He is the Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG), a collaborative clinical research network that prioritizes, designs, and executes clinical research to reduce the public health threat of antibacterial resistance. Dr. Evans is a recipient of the Mosteller Statistician of the Year Award, the Robert Zackin Distinguished Collaborative Statistician Award for contributions to the AIDS Clinical Trials Group (ACTG), an elected member of the International Statistical Institute (ISI), and is a Fellow of the American Statistical Association (ASA), Society for Clinical Trials (SCT), and the Infectious Disease Society of America (IDSA).

Li Chen, PhD is Executive Director, Biostatistics at the Center for Design and Analysis at Amgen. Li has 24+ years of experience in the biopharmaceutical industry and medical research. Li's experience in the design, implementation and analyses of clinical trials includes both early and late phase development across multiple therapeutical areas. Currently she heads up the biostatistics group in hematology oncology and oversees the biostatistics groups in the Japan and Asia-Pacific region and the Inter-continental region, providing leadership for strategic drug development and evidence generation across Amgen's portfolios. Before joining Amgen, Li was a research faculty at the University of Minnesota providing biostatistical support for a national HIV clinical trial network. Li served on the Board of Directors of the Society for Clinical Trials (SCT) and is currently the treasurer of the SCT. Li is a member of the MRCT's Working Group in Diversity in Clinical Trials, ASA Biopharmaceutical Real-World Evidence Scientific Working Group, and the DIA Adaptive Design Scientific Working Group. Li is a Fellow of the Society for Clinical Trials. Li received her ScD in Biostatistics from Harvard University and PhD in Mechanical Engineering from Tufts University.

Stuart Pocock, PhD is Professor of Medical Statistics at the London School of Hygiene and Tropical Medicine. His primary research interest concerns clinical trials, both as regards methodological developments and applied collaboration in major trials. His particular methodologic interests include: standards for the statistical reporting of trials and epidemiological studies, the statistical ethical and organizational principles for data monitoring, including early stopping guidelines, the presentation of time-to-event (survival) data, the pros and cons of non-inferiority trials, and problems of multiplicity in trial reporting, e.g., subgroup analyses, multiple outcomes and covariate adjustment, the role of surrogate endpoints, safety issues and pharmaco-epidemiology. Professor Pocock runs a statistical center for the design, conduct, analysis and reporting of major clinical trials, especially in cardiovascular diseases. He is also a consultant statistician for a wider range of clinical trials in which expert statistical advice is needed, and serves as a statistical member of many trial data monitoring and steering committees. He collaborates internationally, especially with the Cardiovascular Research Foundation in New York and the New England Research Institutes in Boston. He is a frequent lecturer on a variety of clinical trial issues.

Ravi Varadhan, PhD research interests lie in three widely different areas: (i) aging and frailty, (ii) patient-centered outcomes research, and (iii) computational statistics. The work in aging and frailty is aimed at development of theoretical and statistical models for studying frailty as dysregulated homeostasis that increases the vulnerability to stressors. In particular, the focus is on the markers of HPA axis, sympathetic nervous systems and inflammation dynamical systems biology in frailty. Another major focus of mine is on developing statistical methods that inform evidence-based individualized medicine. Dr. Varadhan is interested in identifying factors that are responsible for the heterogeneity in how individuals respond to interventions, which is known as the heterogeneity of treatment effect (HTE). Dr. Varadhan is also developing a new statistical approach for cross-deign synthesis that applies sophisticated statistical methods to combine randomized, controlled trial and registry data to obtain valid evidence for groups such as elderly women, who are under-represented in the trials.

Mark Rothman, PhD is the Director of the Division of Biometrics II. He earned his Ph. D. in Statistics at the University of Iowa in 1990. He then spent the next nine years as a professor at various universities before coming to the FDA in 1999. At the FDA, when he was a reviewer and team leader he was involved in the review on Oncology, Hematology, and Metabolism and Endocrinology products. He has done research in several areas involving the design and analysis of clinical trials and co-authored the book Design and Analysis of Non-Inferiority Trials. He currently leads three Office of Biostatistics Working Groups and Committees in Bayesian Analysis, Drug Trials Snapshots and Pediatric Studies and has served on many working groups and committees.

Stephen Ruberg, PhD 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. Since his retirement, he has formed his own consulting company, Analytix Thinking, which is dedicated to teaching good statistical principles and to consulting on analytical strategies for organizations. He is also an Adjunct Professor of Statistics in the Department of Statistics at Purdue University. He has published widely and lectured internationally on a variety of topics relevant to pharmaceutical research. His work and influence have touched on many important areas such as dose response, evaluation of drug stability data (ICH-Q1E), Statistical Principles for Clinical Trials (ICH-E9), subgroup identification and personalized medicine, Bayesian methods, estimands, data standards and more. 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 (e.g. PhRMA) and the statistical profession (e.g. ASA). He also served as the first Chairman of the Clinical Data Interchange Standards Consortium (CDISC) and received an FDA Commissioner Special Citation for contributions to standards and electronic regulatory submissions. Most notably, he served on a select Advisory Board to Secretary of Health and Human Services Michael Leavitt in the George W. Bush Administration for creating strategies involving the development and use of electronic medical records.

Lisa LaVange, PhD is a professor and the Associate Chair of the Department of Biostatistics. She also serves as the director of UNC's Collaborative Studies Coordinating Center (2006-2011; 2018-present). Dr. LaVange has a broad background in the biostatistics field, including leadership roles in industry (RTI, Quintiles, Inspire Pharmaceuticals); academia (UNC/CSCC); and government (Center for Drug Evaluation and Research at the FDA). She was also the 2018 president of the American Statistical Association. At the CSCC, she has been the lead PI on the HCHS/SOL and SPIROMICS studies and is currently the Coordinating Center PI for the Adolescent Medicine Trials Network for HIV/AIDS Intervention (ATN) and co-PI of the Precision Interventions for Severe and/or Exacerbation-Prone Asthma Network (PrecISE).

Kathleen Fritsch, PhD is a statistical reviewer in the Division of Biometrics 3 in the Office of Biostatistics at CDER/FDA. In addition to review work, she has participated in OB working groups on Drug Trials Snapshots, Subgroup Analysis, Multiple Endpoints, and Labeling.

Thomas A. Louis, PhD is Professor Emeritus of Biostatistics, Johns Hopkins Bloomberg School of Public Health, and Expert Statistical Consultant to the Center for Drug Evaluation and Research at the U. S. Food and Drug Administration. From 2013-2015, he served as Associate Director for Research & Methodology and Chief Scientist at the U.S. Census Bureau. Previous employment included Assistant Professor of Mathematics at Boston University; Associate Professor of Biostatistics at the Harvard School of Public Health; Professor and Head of Biostatistics, University of Minnesota School of Public Health; and Senior Statistical Scientist at RAND. His research covers Bayesian methods, development and application; clinical and field studies; health services research; environmental risk assessment; genomics; and survey methods. He is an elected member of the International Statistical Institute, a Fellow of the American Statistical Association, the American Association for the Advancement of Science (AAAS), and the Institute of Mathematical Statistics; is a National Associate of the National Research Council. Other honors include Honorary Life Member of the International Biometric Society and an Honorary Doctorate from Hasselt University, Belgium. Current service includes Associate Editor, the Annual Review of Statistics and its Application; member of the Technical Advisory Group to the Sub-Saharan Africa Consortium for Advanced Biostatistics Training; the NIH-NIDDK Expert Evaluation Committee of the Alliance of Randomized Trials of Medicine versus Metabolic Surgery in Type 2 Diabetes; the Advisory Committee to the Educational Program on Responsive Survey Design for Efficient Survey Data Collection, Institute for Social Research, University of Michigan; and serves on several clinical trial safety monitoring boards.

Gene Pennello, PhD is a mathematical statistician and researcher at the FDA Center for Devices and Radiological Health (CDRH), Division of Imaging, Diagnostics, and Software Reliability (DIDSR). Previously, he was an FDA team leader, providing peer review, support, and leadership in the statistical review of diagnostic devices – including in vitro diagnostics, diagnostic imaging systems, and digital health software – and radiological therapeutic devices. Gene is a Fellow of the American Statistical Association (ASA), a past chair of the ASA Section on Medical Devices and Diagnostics, and current President of the FDA Statistical Association. Gene earned his Ph.D. in Statistics from Oregon State University and was a postdoctoral training fellow at the National Cancer Institute, Division of Cancer Epidemiology and Genetics.

Donald Berry, PhD is Founder of Berry Consultants, LLC, and a professor in the Department of Biostatistics of the University of Texas M.D. Anderson Cancer Center. He was founding Chair of this department in 1999. Dr. Berry received his Ph.D. in statistics from Yale University, and previously served on the faculty at the University of Minnesota and at Duke University. He has held endowed faculty positions at Duke University and M.D. Anderson. Dr. Berry is a well known developer of statistical theory and methodology. He has designed and supervised the conduct of hundreds of innovative clinical trials, including Bayesian adaptive trials in cancer and other diseases. He has developed Bayesian adaptive designs that efficiently use information that accrues over the course of the trial. These trials minimize sample size while increasing the likelihood of detecting therapeutic activity. A principal focus of his research is the use of biomarkers for learning which patients benefit from which therapies, based on molecular markers and phenotype. In particular, he designed and is a co-PI of I-SPY 2 in high-risk early breast cancer, a trial that was the focus of the two lead articles with two editorials in the July 2016 NEJM. He has designed Phase 3 Bayesian adaptive platform clinical trials in glioblastoma, GBM-AGILE and pancreatic cancer.

Frank Bretz, PhD is a Distinguished Quantitative Research Scientist at Novartis. He has supported the methodological development in various areas of pharmaceutical statistics, including dose finding, estimands, multiple comparisons, and adaptive designs. Frank is an Adjunct Professor at the Hannover Medical School (Germany) and the Medical University Vienna (Austria). He has authored or co-authored more than 150 articles in peer-reviewed journals and four books. Frank is a Fellow of the American Statistical Association.

Marcia Levenstein, PhD recently retired as a VP of Statistics at Pfizer with responsibility for clinical development in the CVMET therapeutic area and globally sponsored Pfizer's China Research & Development Center (CRDC) Statistics organization. While at Pfizer Marcia led the global biometrics organization for Pfizer's marketed medicines clinical research programs and established regional biometrics centers for Latin America, Europe, Asia and China. Marcia has extensive experience in the analysis and interpretation of clinical trial data across numerous therapeutic areas, particularly in Cardiovascular and Anti-infectives. She has served as the statistical leader for regulatory submissions with the responsibility of ensuring biometrics business support of the global pharmaceutical product portfolio. In addition to her role leading Statistics groups, Marcia was a member of Pfizer's team for the clinical trial disclosure policy, and played a key leadership role in defining Pfizer policy on the issue. She was a member of Pfizer's internal steering committee for their Bioethics Advisory Panel and a member of Pfizer's Clinical Trials Policy Group. She is a member of the Stevens Institute Business Intelligence & Analytics Program Advisory Board, which she joined in 2012. She is a member of the ASA Committee on Professional Ethics. Marcia holds BS degrees in Mathematics and Life Sciences from MIT, an MS in Biostatistics form UNC, and an ScD in Biostatistics from Harvard University. She received a Masters in Bioethics form U Penn in 2012.

Frank Harrell, PhD received a PhD in Biostatistics from the University of North Carolina in 1979 under the direction of PK Sen. He was co-managing editor of the journal *Health Services and Outcomes Research Methodology* from 1998-2005, is an Associate Editor of *Statistics in Medicine*, is on the Scientific Advisory Board of *Science Translational Medicine*, is on the Editorial Board of *American Heart Journal*, and has been a long-time consultant to FDA. From 2016-2020 he was Expert Statistical Advisor to FDA CDER Office of Biostatistics for 1/4 of his time. Previously Dr Harrell was on the FDA Cardio-Renal Advisory Committee, a consultant to the FDA Arthritis Advisory Committee, an AHCPR (now AHRQ) study section, and was the director of the SUPPORT (Study to Understand Prognoses Preferences Outcomes and Risks of Treatment) Statistical Center for nine years. SUPPORT concerned end of life care and decision making of primarily elderly patients with one of 8 end-stage diseases. Dr. Harrell is a Fellow of the American Statistical Association and winner of its 2014 WJ Dixon Award for Excellence in Statistical Consulting. He was the 2008 Mitchell Lecturer for the Department of Statistics, Glasgow University. He was the 2012 Presidential Invited Lecturer for WNAR, International Biometric Society, the 2017 Visionary Speaker, Clinical Studies Coordinating Center, University of North Carolina Department of Biostatistics, and the 2018 Distinguished Visiting Scientist, Biostatistics Centre, University of Calgary.

Ilya Lipkovich, PhD is a Sr. Research Advisor at Eli Lilly and Company. Ilya received his PhD in Statistics from Virginia Tech in 2002 and has more than 15 years of statistical consulting experience in pharmaceutical industry. He is an ASA Fellow and published on subgroup identification in clinical data, analysis with missing data, and causal inference. He is a frequent presenter at conferences, a co-developer of subgroup identification methods, and a co-author of the books "Analyzing Longitudinal Clinical Trial Data. A Practical Guide" and "Estimands, Estimators and Sensitivity Analysis in Clinical Trials."

Michael E Griswold, PhD serves as a Professor of Biostatistics & Data Science and Directs the Memory Impairment and Neurodegenerative Dementia (MIND) Center's Science, Evidence and Technology (MINDSET) Core. In addition, he maintains an adjunct faculty appointment in the Department of Biostatistics at the Johns Hopkins University Bloomberg School of Public Health. Dr. Griswold oversees data science and analytic operations in the MIND center for a number of NIH funded cohort studies including: the Atherosclerosis Risk in Communities (ARIC) study, the ARIC Neurocognitive Study (ARIC-NCS), the Genetic Epidemiology Network of Arteriopathy (GENOA) study, the Adiposity, Inflammation and Neurocognitive Decline in African Americans (AINDAA), and the MIND Center-Mayo Clinic Study of Aging (SOA). Dr. Griswold is also the PI of a data science award to improve FAIR data interoperability of the NIA's Baltimore Longitudinal Study of Aging (BLSA). Dr. Griswold founded the UMMC Department of Data Science and served as its founding chair in the establishment of the UMMC School of Population Health. Dr. Griswold has been the PI of multiple population health related data science grants and contracts and has directed numerous biostatistics and data science centers. He has extensive experience in the design, execution, and analysis of clinical, observational, experimental and consortium studies.

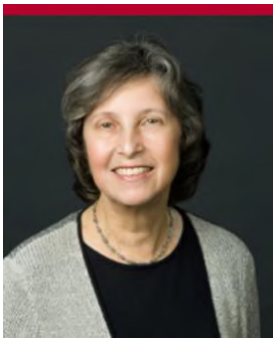
Qi Jiang, PhD is the Head of Biometrics at Seattle Genetics. Before Seattle Genetics, Qi worked at Harvard, Merck, Novartis, and Amgen, accruing many years of diverse experience in drug research, development, global submissions and approvals, and commercialization. Qi is an American Statistical Association (ASA) Fellow and Healthcare Businesswomen's Association (HBA) Rising Star. Qi has over 90 peer-reviewed publications and is co-editor of two books (Quantitative Evaluation of Safety in Drug Development Design, Analysis and Reporting; Benefit-Risk Assessment Methods in Medical Product Development). In addition, Qi is an Associate Editor of Statistics in Biopharmaceutical Research (SBR). Qi was the co-lead of the ASA Safety Working Group and of the Society for Clinical Trials Quantitative Sciences in the Pharmaceutical Industry Benefit:Risk Working Group. Currently Qi is co-leading the ASA BIOP Statistical Methods in Oncology Scientific Working Group.

Thomas Gwise, PhD is the Director of the Division of Biometrics IX in FDA's Center for Drug Evaluation and Research (CDER). The division provides statistical expertise for application review and research associated with therapies for malignant and non-malignant hematology indications. Prior to the formation of Biometrics IX in 2019, Dr. Gwise was deputy director of Biometrics V, supporting review of Oncology therapies. Before joining CDER in 2011, he was a statistical team lead in FDA's Center for Devices and Radiological Health. His research interests include adaptive designs and medical decision making. He received his Ph.D. from the University of Virginia.

John Scott, PhD is 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. He has authored or co-authored numerous articles in areas including Bayesian and adaptive clinical trial design and analysis, drug and vaccine safety, data and text mining, and benefit-risk assessment. He is the CBER lead for 21st Century Cures and PDUFA VI efforts in Complex and Innovative Trial Design and has been heavily involved in a number of FDA's statistical policy and outreach projects, including the 2019 Adaptive Design Guidance for Drugs and Biologics, the 2019 draft Guidance on Interacting with the FDA on Complex Innovative Trial Design, and the ICH E9(R1) expert working group on estimands and sensitivity analyses. Dr. Scott holds a Ph.D. in Biostatistics from the University of Pittsburgh, an M.A. in Mathematics from Washington University in St. Louis, and a B.A. in Liberal Arts from Sarah Lawrence College. He is a Fellow of the American Statistical Association and is currently an Editor of the journal, Pharmaceutical Statistics.

Frank Rockhold, PhD is a Professor of Biostatistics and Bioinformatics at Duke University Medical Center *(Scholars at Duke),* Affiliate Professor of Biostatistics at Virginia Commonwealth University, and Managing Partner of HunterRockhold, Inc. He has diverse research interests and consulting experience in industry and academia including clinical trials design, data monitoring, benefit/risk, and pharmacovigilance and has been a leader in the scientific community in promoting data disclosure and transparency in clinical research. His career includes senior management positions in industry, most recently as Chief Safety Officer for GSK. Dr. Rockhold served as Chairman of CDISC and president of the Society for Clinical Trials. He also served on the initial PCORI Advisory Board and is currently on the boards of the Frontier Science Foundation, Datavant, Athira Pharma, Spencer Healthcare, and an advisor to EMA. Frank holds a BA in Statistics from The University of Connecticut, an ScM in Biostatistics from The Johns Hopkins University, and a PhD in Biostatistics from the Medical College of Virginia at Virginia Commonwealth University. He is an Elected Fellow of both the American Statistical Association, the Society for Clinical Trials, and the Royal Statistical Society. He is an Accredited Professional Statistician, PStat®, and a Chartered Statistician, CStat.

Peter Stein, MD is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters.A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience.Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.



Susan S. Ellenberg, PhD Dr. Ellenberg's research interests have focused on issues in the design and analysis of clinical trials, and on assessment of medical product safety. Particular areas of interest include efficient trial designs, interim monitoring and the operation of data monitoring committees, evaluation of surrogate endpoints, ethical issues in clinical research, and special issues in trials of cancer and AIDS therapies, and of vaccines. She is an associate editor of *Clinical Trials* and of the *Journal of the National Cancer Institute*. Dr. Ellenberg is a fellow of the American Statistical Association, the American Association for the Advancement of Science and the Society for Clinical Trials, and an elected member of the International Statistical Institute. She has served as president of the Society for Clinical Trials and the Eastern North American Region of the International Biometric Society, and has chaired the Statistics Section of the AAAS and the Board of Trustees for the National Institute of Statistical Sciences. Her book on clinical trials data monitoring committees, co-authored with Drs. Thomas Fleming (University of Washington) and David DeMets (University of Wisconsin), was named WileyEurope Statistics Book of the Year for 2002. A second edition was published in 2019

Sarah White, MPH joined the MRCT Center as the Executive Director in January of 2018 and is responsible for developing, defining, and implementing the overall strategy and vision for the Center as well as oversee all management aspects of the MRCT Center functions. Sarah has almost 20 years of experience in human subjects' research including experience at both academic medical centers and industry. Prior to joining the MRCT Center, Sarah was the Director of the Human Research Quality Improvement Program (QI Program) at Partners' Healthcare in Boston, Massachusetts. In this capacity, she was responsible for strategic planning and oversight of the QI Program activities across the human research communities at Partners Healthcare, including Massachusetts General Hospital and Brigham and Women's Hospital. In addition, Sarah oversaw FDA Sponsor-Investigator support and the centralized support of clinical trials registration and disclosure. Sarah is the co-chair of the national Clinical Trials Registration Taskforce, a large consortium of academic medical centers, hospitals and universities that identify best practices, develop tools, and serve as a communication forum associated with the requirements for clinical trials registration and results reporting that affect US academic health centers. Sarah also co-chaired of the Harvard Catalyst Quality Assurance/Quality Improvement Subcommittee from 2010 to 2018. Sarah received her undergraduate degree from Dartmouth College and her MPH from Boston University School of Public Health.