Duke | Robert J. Margolis, MD Center for Health Policy

Public Workshop: Oncology Clinical Trials in the Presence of Non-Proportional Hazards

The National Press Club • Washington, DC
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Biographies

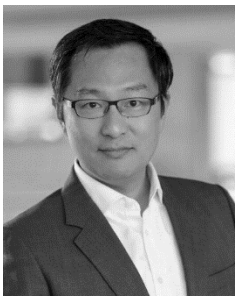
Keaven Anderson is a statistician who has been at Merck Research Laboratories since 2003 and previously worked with Centocor/J&J and with the National Heart, Lung and Blood Institute at the Framingham Heart Study. His doctorate in Mathematical Statistics from Stanford University was followed by post-doctoral work at the Harvard School of Public Health. Keaven is a Fellow of the American Statistical Association. His major interests are in clinical trials, survival analysis and group sequential design. He has been a member of the non-proportional hazards working group since its inception in 2016.

Gideon Blumenthal is Deputy Office Director (acting) of the Office of Hematology and Oncology Products (OHOP) and the Associate Director for Precision Oncology in the FDA Oncology Center of Excellence. Dr. Blumenthal previously worked as a medical officer, and clinical team leader in thoracic oncology and head and neck cancer, where he led a team of oncologists in an unprecedented time for new drug and biologics approvals of targeted therapies and immunotherapies for lung cancer. He was an associate investigator on early phase clinical trials as a fellow and then as an attending physician in the thoracic malignancy branch of the NCI. He has been instrumental in coordinating the efficient review and subsequent approval of several breakthrough targeted therapies and immunotherapies for cancer patients, and has led several key policy initiatives to advance the field of precision oncology and targeted drug development, including initiatives on co-development of drugs with companion diagnostics, novel endpoints, real world evidence, and development of liquid biopsy technologies.

Robert Brown started his pharmaceutical industry in 1977 at McNeil Pharmaceutical, eventually becoming Director of Statistics and Clinical Data Management at The RW Johnson Pharmaceutical Research Institute. Upon leaving Johnson&Johnson in 1992, he established an independent consulting business and partnered with several contract research organizations. Since 2006, he has been Principal Biostatistician at INC Research.

Kunthel By is a biostatistician at the Center for Drug Evaluation and Research at FDA. Over the past several years, he has worked primarily in post-market drug safety. He has extensive experience working with claims data to design and analyze observational studies to assess drug safety, which include cardiovascular and cancer outcomes. He was also involved with FDA's on-going efforts to assess whether prescription opioids formulated with abuse-deterrent properties are effective at reducing abuse and abuse-related outcomes in the community. He recently transitioned from post-market safety to pre-market clinical efficacy studies and is currently a statistical reviewer in the Office of Biostatistics with a focus on

hematology products. Prior to joining FDA, Kunthel worked at SAS as a technical writer and software tester.



Tai-Tsang (Tai) Chen is Head of Biostatistics, Clinical Pharmacology and Pharmacometrics at Bristol-Myers Squibb (BMS). Tai brings two decades of experience in different therapeutic areas, including immuno-oncology, oncology, hematology, immunoscience, fibrosis and cardiovascular drug development. He was the project lead statistician for dasatinib and ipilimumab at BMS, and was also involved in the development of other oncology agents including nivolumab, cetuximab, ixabepilone and paclitaxel. His primary research interests lie in the novel statistical methodology for cancer immunotherapy trials, including innovative approaches in efficacy and safety assessment and prediction of study outcomes. Tai received a Bachelor of Science degree in Psychology from Fu-Jen Catholic University in Taiwan, a Master of Education degree from the State University of New York at Buffalo and his doctoral degree in biostatistics from Columbia University in New York. Prior to becoming a statistician, he served as a clinical psychologist in a psychiatric institute. Currently, he is also serving as an Adjunct Assistant Professor in Biostatistics at Columbia University, and an alumni board member in the Mailman School of Public Health at Columbia University.

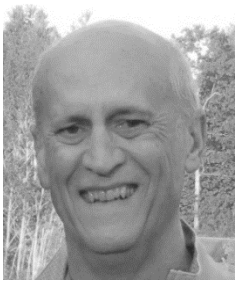
Gregory Daniel is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes form the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.

Andrea Ferris is the CEO of LUNGevity and a member of the Board of Directors. In her role as CEO of LUNGevity, Andrea is responsible for setting and executing the strategic direction of the organization and its science programs. Andrea came to LUNGevity through the merger with Protect Your Lungs, an organization she and her family started to fund lung cancer research following her mother's death from lung cancer in 2008. Before the merger, Andrea founded and built Protect Your Lungs, an organization dedicated to funding research into the early detection of lung cancer. Andrea was instrumental in building PYL's Scientific Advisory Board and establishing its funding process, both of which followed her to the new LUNGevity organization.

In her for-profit career, Andrea has a wealth of management experience. Andrea was the Vice President of Strategy and Growth of Decision Lens, Inc. a company she helped launch in January 2005. Prior to joining Decision Lens, Andrea held a variety of management positions at Johnson & Johnson, including Director of Investor Relations, Manager Corporate Mergers & Acquisitions, and Plant Controller. She also spent several years at McNeil Consumer Products, a J&J subsidiary, in marketing and mergers & acquisitions. Prior to her time at J&J, Andrea worked for Lehman Brothers and Coopers & Lybrand in New York City in both Mergers and Acquisitions and as a CPA. Andrea received her BS in Economics from Wharton with concentrations in Accounting, Decision Sciences, and Finance. She received her MBA from Wharton with concentrations in Finance and Latin American Studies. She served on Washington, DC's Kennedy Center National Committee of Performing Arts and on the Board of ARCS (Achievement Rewards for College Scientists) of Metro DC. She has also served on the Executive Committee of the Board of Directors for DC Metro Boys and Girls Club and has worked with the Ronald McDonald House and the Philadelphia Museum of Art.

Xin (Cindy) Gao is a Mathematical Statistician at CDER in FDA. She earned a Ph.D. in Biostatistics from the University of Michigan, Ann Arbor. She has extensive review experience with New Drug Applications (NDA) and Biologics License Applications (BLA) on hematology and oncology products at FDA. Her statistical methodology interests focus on oncology clinical trial design, survival analysis, surrogacy evaluation and missing data analysis, which led to publications on both statistical and clinical oncology journals, such as statistics in medicine and clinical cancer research.

Susan Halabi is a Professor of Biostatistics and Bioinformatics at Duke University with expertise in oncology clinical trials design and analysis. She has published extensively on prognostic and predictive modelling and on the design and analysis of clinical trials. Dr. Halabi is a member of the National Cancer Institute Genitourinary Committee Steering Committee and a member of the Oncologic Drugs Advisory Committee (ODAC) for the U.S. Food and Drug Administration. She is a co-editor of Oncology Clinical Trials: Successful Design, Conduct and Analysis. Dr. Halabi is as an Associate Editor for Clinical Trials, Statistics in Medicine and Diagnostic and Prognostic Research. She is a fellow of the American Statistical Association and the Society of Clinical Trials. She serves on numerous data safety and monitoring boards and study sections for the National Institutes of Health.



David Harrington has been on the faculty of the HSPH and Dana-Farber for 35 years; he served as the Chair of the Department of Biostatistics and Computational Biology at Dana-Farber between 1998 and 2009. He also served as the co-Director of Undergraduate Studies in the Department of Statistics in the Faculty of Arts and Sciences from 2008 to 2015 and Chair of the Statistics Department in the Harvard Faculty of Arts and Sciences from 2012 to 2015. Professor Harrington has had distinguished career as both a statistical scientist and educator. Dr. Harrington conducts independent research in statistical theory, primarily in survival analysis, and served as the Principal Investigator of the Statistical Coordinating Center of the Cancer Care Outcomes and Surveillance Research Consortium (CanCORS) from 2001 to 2014. CanCORS was a population-based prospective cohort study of approximately 10,000 patients with lung or colorectal cancer. He also served for 10 years as the Principal Investigator of the Coordinating Center Eastern Cooperative Group (now ECOG-ACRIN), a consortium of institutions conducting multi-center cancer

clinical trials. He served as Leader of the Biostatistics Research Program and as Director of the Biostatistics Core Facility for DF/HCC. In 1995 he received the Roger L. Nichols Teaching Award at HSPH. He has also received the Levenson Memorial Teaching Award for Senior Faculty teaching at Harvard College in 2013 and in 2017 he received the Herman Callaert Award for Contributions to Statistical Education. He is a Fellow of the American Statistical Association, the Institute of Mathematical Statistics, and is an elected member of the International Statistical Institute.

Kun He is a mathematical statistician and associate division director of the Division of Biometrics V, Office of Biostatistics, CDER, FDA. He received a Ph.D in statistics from Cornell University, and previously served on the faculties of the University of Minnesota and the University of Kansas. Since joining FDA in 1999, he has provided statistical support for the clinical division of neurology, psychiatry, and hematology and oncology. Currently, he is supporting the Division of Oncology Products 2, Office of Hematology and Oncology Products.

Tianle Hu is a Principal Research Scientist of Statistics at Eli Lilly and Company. Tianle earned his PhD in Biostatistics from the University of Michigan in 2011 and joined Lilly in the same year. At Lilly, Tianle has served in technical and leadership roles supporting early-phase oncology drug development and advanced analytics. Recently, Tianle serves as the Lead Statistician for a phase III molecule development team, providing clinical development and registration support. His research focuses on time to event data analysis in clinical trials and he has published in Biometrika and Lifetime Data Analysis. Tianle is a recipient of the Lilly Research Lab President's Scientific and Diversity Award.

Bo Huang is a Director of Biostatistics at Pfizer. He has more than 10 years of experience across all stages of global clinical development of oncology products and is currently working in the field of immuno-oncology. Over the years, Bo has made important contributions to Pfizer Oncology product development, including crizotinib, inotuzumab, palbociclib, avelumab and other early-stage compounds. Beyond projects, Bo has more than 30 publications in peer-reviewed statistical and medical journals, authored 2 book chapters and contributed to over 40 external oral presentations and short courses. Bo received several poster and paper awards from the American Statistical Association and the International Biometric Society and is an elected Board Director of the International Chinese Statistical Association for 2017-2019. Bo received his PhD in Statistics from the University of Wisconsin-Madison.

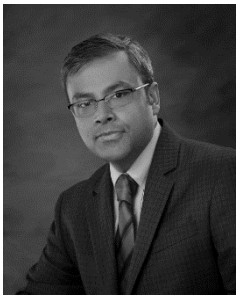
Renee Iacona has been at AstraZeneca since 2001 and has served in a variety of roles all within the department of Biometrics & Information Sciences. Renee received her graduate training at Vanderbilt University where her thesis work was on the Genetics Susceptibility of the Carcinogen Metabolizing Genes to Breast Cancer, which earned her PhD in Pathology and Masters in Public Health (emphasis in Biostatistics). She currently serves AstraZeneca as the Therapeutic Area Head for Oncology/Immuno-Oncology and is accountable for the strategy and delivery of the B&I contributions for the late stage portfolio. Renee also sits on the TA Leadership Team with the other senior leaders in AZ Oncology. She served as a workstream chair for the PhRMA Working Group on Progression-Free Survival and is currently co-chairing the Non-Proportional Hazards Working Group.

Larry Leon is in the Methods, Collaboration and Outreach (MCO) biostatistics group at Roche/Genentech. Larry received her PhD in 2005. Her research interests are in survival analysis and applications of causal inference methods; in particular, challenges with selection bias issues in observational data analyses and RCTs .

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors. It integrates the social, clinical, and analytical sciences to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including such areas as payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and more effective drug and device innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. 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 the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is a member of the National Academy of Medicine and chairs the Academy's Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also 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 as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

Cyrus Mehta is a prominent biostatistician, and Fellow of the American Statistical Association. He co-founded Cytel Inc. in 1987 along with Nitin Patel. Their shared vision was to make modern methods in statistics and operations research accessible to clinical researchers, by creating quality software for statistical analyses. Cyrus's efforts helped establish Cytel as an industry leader in exact statistics, as well as in adaptive and group sequential methods. He remains a driving force behind Cytel's East®, the industry standard software for trial design, simulation and monitoring. As one of the world's leading experts on adaptive clinical trials, Cyrus regularly provides guidance and training to leading pharmaceutical companies, academic collaborators and FDA personnel. He has published more than 100 research articles in scientific journals including JASA, Biometrics, Biometrika, Circulation, The Lancet, The New England Journal of Medicine and Statistics in Medicine. Cyrus is adjunct professor of biostatistics at the Harvard T.F. Chan School of Public Health, and holds degrees from the Massachusetts Institute of Technology and the Indian Institute of Technology at

Bombay. Cyrus has provided groundbreaking innovations in computational statistics for rare events and statistical design of adaptive trials. He and co-authors, Dr. Nitin Patel and Dr. Karim Hirji received the ASA's 1987 George W. Snedecor Award for best paper in biometry. Cyrus was a chief contributor to Cytel's development of permutational algorithms and their applications to categorical data analysis, nonparametric tests, power and sample size calculations, contingency tables analysis and, more generally to inference on the parameters in regression models for categorical data. The same algorithms make it computationally feasible to obtain accurate p-values, confidence intervals and sample-size designs for small or unbalanced data sets and sparse contingency tables. These advances have revolutionized general statistical practices. His recent research focuses on developing group-sequential and adaptive trial methods and supporting software, including adaptive sample size re-estimation or "Promising Zone" designs.



Pralay Mukhopadhyay is an experienced statistician with a proven track record in oncology drug development. He currently works as a Senior Director and Biometrics Team Leader within the immune-oncology (IO) group in AstraZeneca (AZ). During this period, he has made significant contributions in the development of Durvalumab, an anti-PDL1 agent, in Urothelial and Lung Cancer. Prior to joining AZ, he was at Bristol Myers Squibb, where he was involved in their late stage oncology development program. During this time, he was instrumental in the development of several anti-cancer agents in both solid tumors and hematologic malignancies. Dr. Mukhopadhyay has represented his organization in advisory committee meetings with health authorities (HA) across the globe. He has participated in discussions with FDA, Health Canada and ANVISA (Brazilian HA) in broader development challenges of IO agents. He has been an invited speaker at the EMA's workshop on immunotherapy, ISPOR annual meetings, Duke-Industry Statistics Workshop and at the International Society for Biopharmaceutical Statistics (ISBS). He has published in peer reviewed journals and has served as a referee in reputed statistical journals. He received his PhD in statistics from North Carolina State University.

Francesco Pignatti is Head of Oncology, Hematology, Diagnostics Section, Scientific and Regulatory Management Department, Human Medicines Evaluation Division, EMA. Dr. Pignatti earned his M.D. at the University of Rome La Sapienza. In 1995 he became Research Fellow at the EORTC Data Center, Brussels, Belgium, where he was involved in numerous activities, including clinical trial design, conduct, analysis, and reporting. In 1997 he became Medical Advisor for the Gastrointestinal Tract Cancer Cooperative Group and Brain Tumor Cooperative Group. In 1997 he obtained an M.S. in Biostatistics from the University of Limbourg, Belgium. In 1999 he joined the EMA in London. Since 2009, he has held the position of Head of Oncology, Haematology, and Diagnostics in the Human Medicines Evaluation Division.

Mary Redman is an Associate Member in the Clinical Biostatistics Group within the Clinical Research Division at the Fred Hutchinson Cancer Center. She joined the center in 2005. She is also the lead statistician for the Lung Committee within SWOG and is the lead statistician for the Lung-MAP trial, the first of the master protocols launched within the National Clinical Trials Network.

Satrajit Roychoudhury is a Senior Director and a member of Statistical Research and Innovation group in Pfizer Inc. Prior to joining; he was a member of Statistical Methodology and consulting group in Novartis. He started his career as a research statistician in Schering Plough Research Institute (now Merck Co.). He has 10+ years of extensive experience in working with different phases of clinical trial. His primary expertise includes implementation of innovative statistical methodology in clinical trial. He co-authored several publications/book chapters in this area and provided statistical training in major conferences. His area of research includes the use of survival analysis, model informed drug development and Bayesian methods in clinical trials.

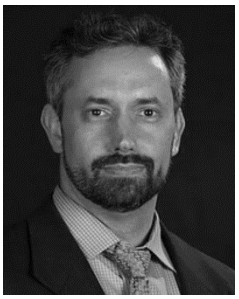
Eric Rubin has focused on cancer drug development for over 25 years, initially as a faculty member at the Dana-Farber Cancer Institute, then as a senior leader of the Cancer Institute of New Jersey, where he served as the Director of the Investigational Therapeutics Division of that institution. His research efforts focused on mechanisms of resistance to DNA topoisomerase-targeting drugs and his laboratory cloned TOPORS, a novel topoisomerase I- and p53-interacting tumor suppressor gene. In 2008 he was recruited to Merck as Vice President, Oncology Clinical Research. Under his leadership, the clinical oncology group underwent a transformational change in an effort to realize the potential of cancer immunotherapy. He led the initial development of the anti-PD-1 antibody pembrolizumab, which was the first anti-PD-1 therapy approved in the U.S., and in the identification of the significant activity of this breakthrough therapeutic across several cancer types. In 2014 Dr. Rubin was asked to head up Oncology Early Development for Merck, and in this role he oversees development of a promising and expansive early pipeline, as well as translational oncology research activities. Dr. Rubin has authored over 120 original, peer-reviewed publications and book chapters related to oncology translational research, clinical trials, and drug development. He has served frequently as a member of National Cancer Institute and American Cancer Society study sections, as well as on program committees for the American Association of Cancer Research (AACR) and the American Society of Clinical Oncology. He is a co-chair of the Cancer Steering Committee of the Biomarkers Consortium, Foundation of the National Institute of Health, a member of the Science Policy and Governmental Affairs Committee for AACR, and was a member of the National Cancer Moonshot Initiative/Blue Ribbon Panel Working Group on Expanding Clinical Trials.

Elad Sharon joined the National Cancer Institute (NCI) as a Senior Investigator in the Cancer Therapy Evaluation Program (CTEP) in December 2011. In that capacity, Dr. Sharon works with academic investigators and industry collaborators to carry out the clinical development of promising new cancer therapies. His current portfolio includes immunotoxins, antibody-drug conjugates, immune checkpoint inhibitors and other targeted and immunotherapy agents. Dr. Sharon co-directs the immunotherapy clinical trials program at CTEP, and he serves as an attending physician in the NCI's Developmental Therapeutics Clinic. Dr. Sharon is frequently called upon to serve as an advisor on issues related to immunotherapy with other groups at the NCI, including the Division of Cancer Prevention and the Division of Cancer Control and Population Sciences. He is also an invited speaker with a national reputation, and he serves on the program committees of major oncology meetings. In addition, Dr. Sharon helps to advance the NCI's efforts in the emerging world of Big Data in oncology, with collaborations with various industry, academic, and government stakeholders ongoing. Dr. Sharon received his M.D. from Baylor College of Medicine in Houston, Texas in 2003. He completed his internal medicine residency at Emory University in 2006 and

continued to work at Emory as a hospitalist and Clinical Instructor prior to his fellowship. Dr. Sharon completed his Hematology/Oncology Fellowship at the NIH in 2011, and during his fellowship, he obtained a Master of Public Health degree at the Harvard School of Public Health in 2009. His research fellowship at the NCI focused on mesothelioma, including a successful effort to modulate the immune response to immunotoxins to enable further administration of these highly immunogenic agents. Dr. Sharon also has worked on several patterns of care projects with the NCI's Healthcare Delivery Research Program using SEER data, and he continues to work with representatives from the NCI's Surveillance Research Program in order to evaluate emerging practice patterns and the economics of cancer care. During his NCI fellowship, he worked as a guest at the Brookings Institution, helping plan and manage panels for the Friends of Cancer Research inaugural Conference on Clinical Cancer Research, whose aim was to find consensus among stakeholders to find solutions to critical questions regarding the future of clinical cancer research. He serves as an associate editor of JNCI Cancer Spectrum and on the editorial board of JCO Clinical Cancer Informatics. In addition, he teaches a course on cancer immunotherapy for the Foundation for Advanced Education in the Sciences and chairs the Economics of Cancer Care pre-ASCO annual meeting educational seminar.

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.

Kay Tatsuoka is currently a Full Development Statistical Lead for Immuno-Oncology at Bristol-Myers Squibb. Previously, he served as Early Development Statistical Lead for Oncology and Immunology. He joined BMS in Fall 2011 after a stint at GSK. He received his PhD in Statistics from Rutgers University and his BS from MIT. Research interests include statistical analysis of biomarkers, adaptive designs.



Marc Theoret is a medical oncologist and serves as the Associate Director (Acting) of Immuno-Oncology Therapeutics in the Oncology Center of Excellence (OCE), FDA. He received his Bachelor of Science degree from Moravian College and his medical degree from the Penn State College of Medicine. Dr. Theoret subsequently completed an internship and residency in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston followed by fellowship training in Hematology/Oncology at the National Cancer Institute (NCI) in Bethesda. While a medical student as a Howard Hughes Medical Institute-National Institutes of Health (NIH) Medical Student Research Fellow and subsequently during fellowship training, he performed basic and clinical research in the Surgery Branch, NCI, to investigate novel

immunotherapeutic strategies to treat patients with melanoma and other advanced solid tumors. Dr. Theoret remains actively engaged in clinical research at the NCI Genitourinary Malignancies Branch. Prior to his current role at FDA, Dr. Theoret has served as primary medical officer, clinical team leader of the Melanoma-Sarcoma team, and scientific liaison for melanoma in the Office of Hematology and Oncology Products, Center for Drug Evaluation and Research. His regulatory research interests include evaluation of novel endpoints for development of cancer immunotherapies and novel trial designs to expedite drug development in oncology.

Samuel Wagner has more than 25 years of experience in health services and outcomes research, with the last 17 years in industry. Samuel held roles of increasing responsibility working in Health Economics and Outcomes Research; currently as an Executive Director in the World Wide Health Economics and Outcomes Research (WWHEOR), leading a group of scientists responsible for early and new Oncology assets and biomarkers in Bristol-Myers Squibb. His extensive work in Health Economics and Outcomes Research has been widely published.

Lijun Zhang is a statistical reviewer in Office of Biostatistics at Center for Drug Evaluation and Research, FDA. As a statistical reviewer, she is primarily involved with reviewing oncology drug related applications submitted to FDA and collaborates extensively with medical researchers on addressing statistical issues encountered in clinical trials designs and analyses. Prior to joining FDA, Dr. Zhang has worked at Dana-Farber Cancer Institute, focusing on clinical trial design and analysis in hematology disease area. Dr. Zhang received her Ph. D degree in Applied Statistics at University of Memphis.