

FDA-AACR Real-world Evidence Workshop

July 19, 2019 | Bethesda, MD

Workshop Cochairs

Pallavi Mishra-Kalyani, PhD, *U.S. Food and Drug Administration*



Pallavi Mishra-Kalyani, PhD, is a Team Leader in the Division of Biometrics V, Office of Biostatistics which supports Office of Hematology Oncology Products at the Center for Drug Evaluation and Research (CDER). Since joining the Food and Drug Administration (FDA) in 2015, Dr. Mishra-Kalyani has contributed to the efforts to understand and address the statistical issues related to the potential use of real-world data and real-world evidence for regulatory purposes. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design. She has participated at several statistics and oncology workshops, conferences, and working groups on these topics. Dr. Mishra-Kalyani received her PhD in Biostatistics from Emory University and her Master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University.

Deborah Schrag, MD, MPH, *Dana-Farber Cancer Institute*



Dr. Deb Schrag is medical oncologist and a health services researcher at the Dana-Farber Cancer Institute. She is Chief of the Division of Population Sciences and a Professor at Harvard Medical School. Dr. Schrag's research focuses on comparative effectiveness and improving the quality of cancer care through interventions directed at the individual patient, health system and policy level. Dr. Schrag is also a clinician with longstanding focus on gastrointestinal cancers, particularly colorectal cancer and leads the largest Phase III national trial in rectal cancer. Dr. Schrag is a leader in the development of systems to integrate patient reported outcomes into both clinical trials and routine oncology care. A major focus of her work is developing strategies to better integrate the patient perspective in understanding the effectiveness and toxicity of cancer treatments. She is currently working in collaboration with multiple cancer centers to develop capacity for reliable measurement of "Real World" clinical outcomes to gain knowledge from cancer patients who receive treatment outside the clinical trial context. She is the PI of a Moonshot award from the NCI to engage patients in systematic reporting of their symptoms during cancer treatment. She leads a training grant to develop careers of cancer-focused population scientists and the Cancer Care Delivery Research program at the Dana Farber Harvard Cancer Center. Dr. Schrag is a fellow of the American Society of Clinical Oncology, an elected member of the Association of American Physicians, and an Associate Editor of the Journal of the American Medical Association.

Sean Khozin, MD, MPH, U.S. Food and Drug Administration



Dr. Khozin is a physician-data scientist focused on building solutions at the intersection of biomedicine, healthcare and connected technologies. A thoracic oncologist, Dr. Khozin currently serves as associate director of the Oncology Center of Excellence at the U.S. Food and Drug Administration (FDA), leading the Center's bioinformatics initiatives. He is also director of Information Exchange and Data Transformation (INFORMED; www.fda.gov/INFORMED), the FDA's first data science and technology incubator for collaborative regulatory science research focused on supporting innovations that enhance the agency's mission of promotion and protection of public health. The research portfolio of INFORMED includes investigations into the use of real-world data for clinical evidence generation and

decentralized clinical trials, examination of the utility of biosensors and the internet of things to quantify intrinsic and extrinsic (e.g., environmental) factors influencing the patient's experience, development of applications for machine learning and artificial intelligence in regulatory science and drug development, and testing the utility of decentralized technologies such as blockchain to enable secure exchange of health data at scale.

Previously, Dr. Khozin owned and managed a multidisciplinary healthcare delivery network in New York City as a practicing physician and was an entrepreneur specializing in building health information technology systems with telemedicine, point-of-care data visualization and advanced analytics capabilities.

Workshop Speakers and Panelists

Jeff Allen, PhD, Friends of Cancer Research



Jeff Allen, PhD serves as the President and CEO of Friends of Cancer Research (Friends). During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. As a thought leader on many issues related to the U.S. Food and Drug Administration, regulatory strategy, and healthcare policy, he is regularly published in prestigious medical journals and policy publications, and has contributed his expertise to the legislative process on multiple occasions. Recent Friends initiatives include the establishment of the Breakthrough Therapies designation and the development of the Lung Cancer Master Protocol, a unique partnership that will accelerate and optimize clinical trial

conduct for new drugs. Dr. Allen received his PhD in cell and molecular biology from Georgetown University, and holds a Bachelors of Science in Biology from Bowling Green State University.

Laleh Amiri-Kordestani, MD, U.S. Food and Drug Administration



Dr. Amiri-Kordestani is the associate director of the Division of Oncology Products 1 (DOP1) in the Office of Hematology Oncology Products in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). Dr. Amiri-Kordestani earned her medical degree from the University of Tehran Medical Sciences. She did a year of post-doctoral research fellowship in Molecular Genetics Laboratory at the National Institutes of Health. She completed a residency in internal medicine at the Georgetown University/Washington Hospital Center, followed by a fellowship in hematology and oncology at The National Cancer Institute. Under the direction of Dr. Sandra Swain, she became familiar with the design and implementation of breast cancer oncology clinical trials and

at the NCI, she worked with Dr. Susan Bates focusing on early phase clinical trials and wrote two clinical protocols for patients with breast cancer and brain metastases. At the FDA, Dr. Amiri-Kordestani served as medical officer and clinical team leader of the Breast Cancer Group prior to assuming her role as associate director in DOP1. She is also an assistant professor at Georgetown University Hospital where remains clinically active, practicing inpatient medicine.



Gideon M. Blumenthal, MD, U.S. Food and Drug Administration



Gideon M. Blumenthal, MD, is deputy director for the Oncology Center of Excellence. He is board certified in internal medicine, medical oncology, and hematology by the American Board of Internal Medicine. He earned his undergraduate degree from Washington University in St Louis and his medical degree from University of Maryland School of Medicine. He completed an internal medicine residency at University of Maryland, followed by a hematology/oncology fellowship at the National Cancer Institute. Blumenthal previously worked as a medical officer, clinical team leader in thoracic oncology and head and neck cancer, and scientific liaison for lung cancer at FDA. He was an associate investigator on several phase 1 and phase 2 clinical trials as a fellow and then as an adjunct attending physician in the thoracic malignancy branch of the NCI. Blumenthal serves as the OHOP scientific liaison to the American Society for Clinical Oncology, is a member of the Foundation for the NIH Biomarker Consortium Cancer Steering Committee, and served on the White House Cancer Moonshot Liquid Biopsy Blood Profiling Atlas in Cancer (Blood-PAC) committee. His research has focused on investigating novel intermediate endpoints and biomarkers to better inform oncology drug and diagnostic development and clinical trial design.

Oliver Bogler, PhD, ECHO Institute



Dr. Bogler joined the ECHO Institute in 2018 to focus on the execution of its strategy to touch one billion lives by 2025 by democratizing scarce expert knowledge to improve services to the underserved in healthcare, education, and beyond. He works to empower Project ECHO partners who share his passions for making a difference in the world with a focus on cancer.

Oliver studied Natural Sciences at Cambridge University, completed his PhD at the Ludwig Institute for Cancer Research in London, and did post-doctoral training at the Salk Institute, and the Ludwig Institute, San Diego Branch. He held faculty appointments at Virginia Commonwealth University, Henry Ford Hospital, and the University of Texas MD Anderson Cancer Center where he also served as Director of Basic Research for the Brain Tumor Center. His research focused on EGFR signaling and novel platinum compounds in glioblastoma.

In 2010, he became MD Anderson's Vice President for Global Academic Programs and managed a network of 35 sister institutions in 22 countries, with a total investment in global cancer collaborations of \$12M over 7 years and an annual conference with over 800 participants. In 2011, he was also appointed Senior Vice President for Academic Affairs where he stewarded MD Anderson's education mission and accreditation and oversaw 300 people, who delivered support for 1,700 faculty and more than 2,000 trainees and students.

In 2012 Oliver was diagnosed with stage III breast cancer and shared his journey on a blog at malebreastcancerblog.org, and has advocated for more research inclusiveness in clinical research for the 1% of breast cancer patients who are men.

Rohit Borker, PhD, Novartis



Rohit Borker, PhD, is currently the Vice President and Head, Health Economics and Outcomes Research (HEOR), U.S. Oncology at Novartis. In this role, he leads the HEOR organization in generation of evidence for U.S. organized customers including payers and integrated delivery networks. Additionally, his team is also involved in innovative research involving value of oncology care, real world data and analytics, and patient centered initiatives. Before joining Novartis, Rohit was with Boehringer Ingelheim's (BI) HEOR group leading their Oncology and Respiratory therapy areas, where he managed a team of health outcomes researchers with responsibilities to develop evidence in support of value proposition for BI's products. Prior to BI, Rohit was at GlaxoSmithKline where he led a field team of Health Outcomes Liaisons with responsibilities for GSK's General Medicine and Vaccine Portfolio. During this time, he also served on National Quality Forum's (NQF) Oncology Technical Advisory Panel, which evaluated methodologies to assess resource utilization and cost as it relates to oncology management. In addition to oncology, Rohit



has covered multiple therapeutic areas including respiratory, nephrology, and auto-immune disorders. Before joining the industry, Rohit completed his Doctoral work at the West Virginia University. His thesis evaluated breast cancer risk in West Virginia Medicaid population using validated risk algorithm and developed economic model to estimate cost effectiveness of chemopreventive strategy. During his Doctoral work, Rohit also served as the research lead for CDC's and American Pharmaceutical Association's Pharmacy Immunization Project. His post-thesis work involves numerous database studies including cost of event studies, early and late stage economic modeling, patient reported outcomes application and analyses. He was part of the original working group that eventually developed the COPD-Assessment Questionnaire (COPD-AQ). He has multiple publications including papers in Value in Health, Pharmacoeconomics, Clinical Genitourinary Cancer, BMC Cancer, Annals of Asthma, Allergy, & Immunology, and Journal of Health & Social Policy.

William Capra, PhD, Genentech



Bill Capra, PhD, is Senior Group Director of Real World Data, Oncology for Genentech/Roche. Bill leads a group of over 30 Data Scientists located in Basel, Switzerland, Welwyn, England, and South San Francisco, USA. Bill joined Genentech 13 years ago in the Biostatistics function after a decade at Chiron. His focus in both Biostatistics groups was in the design and analyses of clinical trials, with a focus primarily on the oncology and infectious diseases therapeutic areas. In 2014 he joined Roche's newly formed Data Science function when it was launched to build a group to find innovative uses for real world data in oncology drug development. Bill has a BS in Mathematics from Drexel University and a PhD in Statistics from the University of California, Davis.

Andrea Coravos, Elektra Labs



Andy Coravos (@andreacoravos) is the CEO/co-founder of Elektra Labs, building a digital medicine platform with an initial focus on digital biomarkers for decentralized clinical trials, and a member of the Harvard-MIT Center for Regulatory Sciences. Formerly, Andy served as an Entrepreneur in Residence at the FDA working in the Digital Health Unit (DHU), focusing on the Pre-Cert program and policies around software and AI/ML. Previously, she worked as a software engineer at Akili Interactive Labs, a leading digital therapeutic company. Before grad school, Andy worked at KKR, a private equity firm, and at McKinsey & Company, a management consulting firm, where she focused on the healthcare industry. She serves on the Board of the Digital Medicine Society (DiMe), and she's an advisor to the Biohacking Village at DEF CON.

Jacqueline Corrigan-Curay, JD, MD, U.S. Food and Drug Administration



Jacqueline Corrigan-Curay, JD, MD, serves as Director of CDER's Office of Medical Policy (OMP). She leads the development, coordination, and implementation of medical policy programs and strategic initiatives. She works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes.

Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI), at the National Institute of Health's (NIH) and served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and a practicing attorney in Washington, D.C.

Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical



assistant professor of medicine. She continues to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, D.C.

William S. Dalton, PhD, MD, M2Gen



Dr. William (Bill) S. Dalton is Founder and Executive Chair of M2Gen, a national biotechnology subsidiary of the Moffitt Cancer Center. He is the past President, CEO & Center Director of Moffitt Cancer Center, an NCI-Designated Comprehensive Cancer Center (2002-2012). Prior to joining Moffitt, Dr. Dalton was the Dean of the University of Arizona College of Medicine. His research interests include development of information systems to allow aggregation, organization, and sharing of patient data in real time to enhance discovery and delivery of evidenced-based precision medicine. For his leadership in the area of personalized medicine, Dr. Dalton was recognized as the 2010 recipient of the Personalized Medicine Coalition's National Leadership in Personalized Medicine Award. Dr.

Dalton's basic and translational research interests focus on molecular mechanisms of drug resistance and drug discovery. He has over 200 publications, serves on several editorial boards, and has numerous patents in the fields of drug discovery and computer/information networking. He has served on numerous not-for-profit boards, and is the past-Chair of the Personalized Medicine Coalition and is the current Board Chair of the Institute of Human and Machine Cognition. He is also the past-President of the Association of American Cancer Institutes.

Ruthanna Davi, PhD, Acorn AI



Ruthie Davi is a Statistician and Vice President at Acorn AI, a Medidata company, and has a background in pharmaceutical clinical trials with more than 20 years working as a Statistical Reviewer, Team Leader, and Deputy Division Director in the Office of Biostatistics in CDER at FDA. At the FDA, Ruthie participated in the statistical review and provided recommendations regarding FDA marketing approval for numerous New Drug and Biologic Licensing Applications. With a particular interest in pediatric clinical trials, she was an active member of FDA's Pediatric Review Committee. At Acorn AI Ruthie is part of a team creating analytical tools to improve the efficiency and rigor of clinical trials, an example of which is the Synthetic Control work. Ruthie holds a PhD in Biostatistics from George Washington University.

James Gulley, MD, PhD, FACP, National Cancer Institute



Dr. James Gulley is an internationally recognized expert in immunotherapy for cancer. He graduated from Loma Linda University in California with a PhD in microbiology in 1994 and an MD in 1995. As part of this eight-year MD/PhD Medical Scientist Training Program, he completed a dissertation on tumor immunology. He completed his residency in Internal Medicine at Emory University in 1998, followed by a Medical Oncology fellowship at the National Cancer Institute (NCI).

Dr. Gulley serves within the Center for Cancer Research (CCR) of the National Cancer Institute as Chief of the Genitourinary Malignancies Branch (GMB), the Director of the Medical Oncology Service (CCR), and also Head of the Immunotherapy Section within the GMB. He has been instrumental in the clinical development a number of therapeutic cancer vaccines. In addition, he serves as the coordinating Principle Investigator (PI) of several international trials of immunotherapies, one of which led to FDA approval of avelumab (Bavencio), now approved for Merkel Cell carcinoma, bladder cancer, and renal cancer. He leads a number of combination immunotherapy studies.

Dr. Gulley has received numerous awards including the Presidential Early Career Award for Scientists and Engineers (PECASE), the highest award bestowed by the U.S. government on outstanding scientists early in their careers. Dr. Gulley serves on many national and NIH boards and committees. He has been an investigator on more than 120 clinical trials, authored more than 250 scientific papers or chapters, serves on a number of editorial boards of scientific journals and has made hundreds of presentations at national / international meetings.



Robert Grossman, PhD, *University of Chicago*



Robert L. Grossman is the Frederick H. Rawson Distinguished Service Professor in Medicine and Computer Science and the Jim and Karen Frank Director of the Center for Translational Data Science at the University of Chicago. He has also served as the chief research informatics officer of the Biological Sciences Division since 2011. He is the principal investigator for the National Cancer Institute Genomic Data Commons (GDC), a platform for the cancer research community that manages, analyzes, integrates, and shares large-scale genomic datasets in support of precision medicine. The GDC was used by more than 100,000 researchers in the past year. He has also built data commons to support research in other areas, including cardiology, infectious diseases, neuroscience, and the environment. He serves as chair of the Open Commons Consortium, a nonprofit that develops and operates data commons to support research in science, medicine, health care, and the environment.

Weili He, PhD, *AbbVie*



Dr. Weili He is a Senior Director, head of Global Medical Affairs Statistics, Data and Statistical Sciences at AbbVie Inc. She has a PhD in biostatistics. Prior to joining AbbVie, she worked in Clinical Biostatistics at Merck & Co., Inc. for over 20 years. Weili has published extensively in the areas of adaptive designs and benefit-risk assessment and is the author of more than 50 peer-reviewed publications in statistical and medical journals and the lead Editor of two books. In her current role at AbbVie in the last few years, Weili has been extensively involved in strategic and methodologic research in real-world data and real-world evidence (RWE), and has been involved in the review and development of numerous real-world studies at AbbVie. Weili is the co-founder and co-chair of the American Statistical Association Biopharmaceutical Section RWE Scientific Working Group, Chair-Elect 2020 of the American Statistical Association Biopharmaceutical Section, an Associate Editor for Statistics in Biopharmaceutical Research, and an elected Fellow of the American Statistical Association.

Jonathan Hirsch, *Syapse*



Jonathan Hirsch is the Founder and President of Syapse, a market leader in precision oncology solutions. Jonathan works closely with healthcare providers and ecosystem partners to create products that improve patient outcomes through precision medicine. Jonathan's work includes catalyzing national cancer data sharing networks, serving on the White House Cancer Moonshot Data Sharing Working Group and the Biden Cancer Initiative Data Sharing Working Group, and chairing the Data Committee for GBM AGILE, a global initiative to find a cure for brain cancer. Before founding Syapse, Jonathan worked in neuroscience commercial development at Abbott Laboratories. Jonathan received an MSci in Neuroscience from Stanford University and an AB in Biology and Political Philosophy from the University of Chicago.

Cynthia Huang, MD, MBA, *Merck*



Cynthia Huang Bartlett, MD, MBA, is currently the Associate Vice President, Global Medical Affairs for Merck Oncology. She has extensive oncology drug development experience in the pharmaceutical industry. Previously, she was the Global Medical Strategy Head for Ibrance at Pfizer Oncology. Cynthia led the development and global launches for three new oncology drugs: Lapatinib, an anti-HER2+ agent for breast cancer; Crizotinib, an ALK inhibitor for ALK translocation in lung cancer; and Palbociclib, a CDK4, 6 inhibitor for breast cancer. Her clinical research interests include real-world pragmatic study designs in oncology. Early this year, she had the honor of leading the team that was able to leverage real-world evidence to expand a product label for Ibrance into male breast cancer, a rare population. She received her education and training at Fu Dan University in China and Washington University in St. Louis, respectively.



Michael A. Kelsh, PhD, MPH, Amgen



Dr. Michael Kelsh is currently an Executive Director for Amgen's Center for Observational Research (CfOR), Oncology Therapeutics Area. Dr. Kelsh oversees epidemiologic research evaluating the development, efficacy, and safety of Amgen's oncology therapeutics. Dr. Kelsh is also an Adjunct Professor at the UCSF Department of Epidemiology and Biostatistics where he teaches a graduate seminar in pharmacoepidemiology and a Visiting Professor at Aarhus University, Department of Clinical Epidemiology. Dr. Kelsh's research has included numerous studies of cancer, respiratory and neurological diseases, injury/musculoskeletal conditions, pharmacoepidemiologic studies, and numerous occupational and environmental exposures with research findings published in over 60 peer-reviewed scientific articles.

Albert L. Kraus, PhD, Pfizer



Albert Kraus is currently the Global Regulatory Portfolio Lead for Women's and Gastrointestinal Cancers as well as the Global Franchise Regulatory Lead for IBRANCE (palbociclib) within Pfizer Research and Development. In this role he works with teams across oncology to help ensure the development and execution of robust registration development strategies and effective Health Authority interactions. Just prior to joining Pfizer in early 2011, Albert held Vice President Management Team roles leading Regulatory Science, Pharmacovigilance, Quality Assurance, and/or Clinical Development at Onyx, Proteolix and Kosan Biosciences (San Francisco Bay area Biotech Companies acquired by Amgen and Bristol Myers Squibb). Previously, Albert held positions of increasing responsibility at Bristol-Myers Squibb (including 4 years in a European role based in Belgium) culminating as a Group Director leading Worldwide Oncology Regulatory Affairs and FDA liaison activities. Albert began his industry career at Procter & Gamble and while there held positions of increasing responsibility in the pharmacology, toxicology, clinical safety, and regulatory science areas.

Albert has worked primarily in Oncology, Immunology, Metabolic, and Dermatology therapeutic areas and participated in the development of numerous small molecules and biologicals from research through end of life cycle stages. Albert received a BA from Hamilton College, with concentrations in Biology and Economics, and earned a PhD in biochemical toxicology from the University of Michigan.

Steven J. Lemery, MD, MHS, U.S. Food and Drug Administration

Dr. Lemery is the Associate Director of the Division of Oncology Products 2 within the Office of Hematology and Oncology Products in CDER/FDA. In addition to duties regarding general drug development for patients with cancer, Dr. Lemery has also focused on tissue-agnostic development and biosimilar development. Prior to assuming the role of Associate Director, he served as the Team Leader (Lead Medical Officer) for the gastrointestinal malignancies team. Dr. Lemery completed his clinical training in hematology and medical oncology at the National Institutes of Health in Bethesda, Maryland. Dr. Lemery also graduated with a Master of Health Sciences in Clinical Research degree awarded by the Duke University School of Medicine (joint NIH/Duke program).

Mark Levenson, PhD, U.S. Food and Drug Administration



Mark Levenson is currently the Director of the Division of Biometrics 7 in the Office of Biostatistics/Office of Translational Sciences/Center for Drug Evaluation and Research of the US Food and Drug Administration (FDA). At FDA, he has been the primary reviewer or secondary reviewer on many major pre-market and post-market drug safety problems. He contributes to statistical policy and guidance development in the areas of drug safety and real-world evidence. He is a member of the FDA Drug Safety Oversight Board and the Real-World Evidence Framework Committee. Dr. Levenson received a PhD in Statistics from the University of Chicago and B.A. from Cornell University in Mathematics.



Neal J. Meropol, MD, Flatiron Health



Neal J. Meropol, MD, is a medical oncologist and clinical investigator who serves as Vice President of Research Oncology at Flatiron Health. In this role, he leads efforts to leverage Flatiron's technology platforms and nationwide provider network to gain insights from real world data that accelerate research and improve quality of care for cancer patients. Prior to joining Flatiron in 2017, he was Professor and Chief of the Division of Hematology and Oncology at University Hospitals Cleveland Medical Center and Case Western Reserve University, and Associate Director for Clinical Research at the Case Comprehensive Cancer Center.

Dr. Meropol's scientific contributions span drug development and health services research, including evaluation of new agents, predictors of response and outcome, development of tools to overcome barriers to clinical trial participation, and assessment of the economic impact of care. He is currently a member of the NCI Clinical Trials and Translational Research Advisory Committee (CTAC), and previously served two terms as Chair of the National Cancer Institute Gastrointestinal Cancer Steering Committee. Dr. Meropol completed a four-year term as an elected member of the American Society of Clinical Oncology (ASCO) Board of Directors. A committed educator, Dr. Meropol served for 10 years as faculty on the AACR/ASCO Methods in Clinical Research Vail Workshop, and currently serves as chair of the ASCO Leadership Development Program. He has authored more than 250 manuscripts, book chapters, and editorials related to cancer prevention, treatment, decision making, and health economics. Dr. Meropol received his undergraduate degree from Princeton University in Philosophy, and MD from Vanderbilt University. He was a resident in Internal Medicine at Case Western Reserve University, and completed hematology and medical oncology fellowships at the University of Pennsylvania. He spent a sabbatical at the Leonard Davis Institute of Health Economics at the Wharton School of the University of Pennsylvania.

Gary Palmer, MD, JD, MBA, MPH, Tempus



Dr. Palmer is a veteran of the pharma and biotech industry. He has over twelve years' experience specifically in the genomic space. Currently, he is the Chief Medical Officer at Tempus. Previously, he was the Chief Medical Officer at NantHealth in Los Angeles, CA. Before that, he was Senior Vice President, Medical Affairs, at Foundation Medicine. Before Foundation Medicine, he was Vice President of Medical Affairs at Genomic Health where he directed the medical aspects of the Oncotype DX Breast Cancer Assay. After Genomic Health, he served as Chief Medical Officer of On-Q-ity, a circulating tumor cell company. Prior to Genomic Health, Dr. Palmer had extensive experience in the pharmaceutical industry, including roles as Executive Director at Kosan Biosciences and at

Salmedix, Inc. where he spent time in early drug development. Previously, he spent five years at Amgen where he was involved in the development and commercialization strategies of Neulasta and Aranesp.

Before his roles in industry, Dr. Palmer served as a medical oncologist in both academia and the community setting. Dr. Palmer was director of the Medical Breast Service at the University of California, Davis, Cancer Center and Chief of Medical Oncology at the Mercy Health System, Sacramento, California. For nine years he was on the adjunct faculty of the University of California, Davis, Graduate School of Management where he taught "Management of Biotechnology" to MBA students.

Dr. Palmer is a magna cum laude graduate of Yale University and a graduate of the Stanford University School of Medicine. He did his internal medicine training at the Boston City Hospital and his oncology fellowship at the Massachusetts General Hospital. He has a Masters in Business Administration (MBA) from the University of California, Davis, and a Masters in Public Health (MPH) from U.C.L.A. As well, Dr. Palmer holds a J.D. degree and is admitted as an attorney to the State Bar of California.

Dr. Palmer is married to Liz and between them they have five children. He is an avid runner and a five-time winner on the television show "Jeopardy!"



Frank W. Rockhold, PhD, *Duke Clinical Research Institute*



Frank 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. His 40+-year career includes senior research positions at Lilly, Merck, and GlaxoSmithKline, where he retired as Chief Safety Officer and Senior Vice President of Global Clinical Safety and Pharmacovigilance. He has held faculty appointments at six different universities. Dr. Rockhold served for 9 years on the board of directors of the non-profit CDISC, most recently as Chairman, and is past president of the Society for Clinical Trials. He is a past member of the PCORI Clinical Trials Advisory Panel and is currently on the board of the Frontier Science and Technology Research Foundation and a technical advisor to EMA.

Dr. Rockhold has diverse research interests and consulting experience in industry and academia including clinical trials design, data monitoring, benefit/risk, safety and pharmacovigilance and has been a leader in the scientific community in promoting data disclosure and transparency in clinical research. Frank is widely published in major scientific journals across a wide variety of research topics.

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. Frank is an Elected Fellow of both the American Statistical Association and the Society for Clinical Trials, a Fellow of the Royal Statistical Society, an Accredited Professional Statistician, PStat[®], and a Chartered Statistician, CStat.

Wendy S. Rubinstein, MD, PhD, *CancerLinQ*



Dr. Wendy Rubinstein is Deputy Medical Director of CancerLinQ[®], a not-for-profit subsidiary of the American Society of Clinical Oncology (ASCO). CancerLinQ is ASCO's physician-led web-based health information technology platform that collects and analyzes data from the electronic health records of participating practices across the United States to help improve the quality of care for patients with cancer. Dr. Rubinstein provides genomics expertise to CancerLinQ and organizes its scholarly work.

Dr. Rubinstein directed academic cancer genetics programs for 15 years at three NCI-designated Comprehensive Cancer Centers. During her tenure as a Senior Scientist at the National Institutes of Health, Dr. Rubinstein launched and directed the NIH Genetic Testing Registry (GTR), now the most comprehensive publicly available information resource about genomic tests in the world. As Chief of Medical Genetics and Human Variation at the National Center for Biotechnology Information (NCBI), she was responsible for flagship information resources including ClinVar, dbSNP, dbGaP, and GTR. Dr. Rubinstein was a representative to the NIH-FDA-CMS Trilateral Genomic Medicine Workgroup and FDA-NIH Interagency Task Force on Laboratory Developed Tests, and received the NIH Director's Award from Dr. Francis Collins for developing and launching GTR.

An NIH Medical Scientist Training Program scholarship awardee, Dr. Rubinstein earned her MD and PhD degrees at the Mount Sinai School of Medicine in New York City (now Icahn). She holds dual board certification in clinical genetics and clinical molecular genetics (ABMG) and is a Fellow of the American College of Medical Genetics (FACMG) and the American College of Physicians (FACP). She has authored publications on gene discovery (SDHD), sequence variant interpretation, genomic population screening, computerized familial risk assessment, pharmacogenomics, genetic modifiers, genomic information resources, clinical practice guidelines, and health information technology.



Mark Shapiro, PhD, MBA, *xCures*



Mark Shapiro is widely recognized as an expert on the business of clinical research and is frequently quoted in the press, including *Outsourcing Pharma*, *PharmaVoice*, and *CenterWatch*. His comments have also been featured in articles in the *New York Times* and *Raleigh News & Observer* on topics pertaining to the business of drug development. He serves as Vice President of Clinical Development at *xCures*, and is a Partner at *Pharma Initiatives*, an innovation focused management consulting firm dedicated to clinical research, drug development, and medical affairs. Mark has led strategic planning, growth, and change management initiatives at many pharmaceutical, biotech and clinical research organizations.

Previously, Mark was Senior Vice President of Operations at a global, oncology-focused CRO, where he was led an operations team of about 500 drug development professionals in more than 30 countries worldwide, and led a portfolio of more than 100 active clinical trials. He was previously a management consultant at *Campbell Alliance*, now *Syneos Health Consulting*, in the Clinical Development and Medical Affairs Practice, where he worked with many global CROs and biopharma companies on R&D innovation strategy. Dr. Shapiro is a pharmacologist, and holds an MBA from *Duke University's Fuqua School of Business*. Mark has received numerous certifications in clinical research, regulatory affairs, and healthcare management.

Elad Sharon, MD, MPH, *National Cancer Institute*



Elad Sharon, MD, MPH, joined the NCI Cancer Therapy Evaluation Program (CTEP) in December 2011 as a Senior Investigator in the Investigational Drug Branch, where he works with academia and industry to develop promising cancer therapies. His portfolio includes antibody-drug conjugates, immune checkpoint inhibitors and other agents. Dr. Sharon co-directs immunotherapy trials at CTEP and serves as an attending physician in NCI's Developmental Therapeutics Clinic (DTC). As part of his work for CTEP and the DTC, Dr. Sharon has assisted the NCI in planning major initiatives to study the intersection of the fields of cancer immunotherapy treatment and autoimmunity. Dr. Sharon is the co-Principal Investigator on a trial of nivolumab for patients with autoimmune diseases (NCI Trial 10204), and he is assisting the Alliance for Clinical Trials in Oncology in developing an immune-related Adverse Events (irAE) Biorepository to better characterize and learn from irAEs as they occur.

Dr. Sharon received his MD from *Baylor College of Medicine* in Houston, Texas in 2003. He completed his internal medicine residency at *Emory University* in 2006 and his Hematology/Oncology Fellowship at the *NIH* in 2011, while obtaining a Master of Public Health degree at the *Harvard University* in 2009. His fellowship research focused on clinical trials in mesothelioma. Dr. Sharon works on patterns of care projects with NCI's Healthcare Delivery Research Program using SEER data and with NCI's Surveillance Research Program to evaluate emerging practice patterns and the economics of cancer care. He previously worked as a guest at the *Brookings Institution*. He is as an associate editor of *JNCI Cancer Spectrum* and on the editorial board of *JCO Clinical Cancer Informatics*.

Rajeshwari Sridhara, PhD, *U.S. Food and Drug Administration*



Rajeshwari Sridhara, PhD, 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 U.S. Food and Drug Administration (FDA) in 1999. Dr. Sridhara has contributed to 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.

Joohee Sul, MD, U.S. Food and Drug Administration

Dr. Sul is a medical officer in the Office of New Drugs in the Division of Oncology Products 2 of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration, where she is a brain and CNS malignancies scientific liaison and medical reviewer.

A board-certified neurologist, she received her M.D. at the University of Rochester School of Medicine and Dentistry and completed a fellowship in neuro-oncology at Memorial Sloan-Kettering Cancer Center. She was a senior instructor for two years at the University of Rochester.

