Overall Survival in Oncology Clinical Trials

Tuesday, July 18, 8am-5pm ET
Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814
Congressional Ballroom

Workshop Co-Chairs (Alphabetically by Last Name)

Kenneth C. Anderson, MD, FAACR, *Dana-Farber Cancer Institute, Moderator of Session 1*

Kenneth C. Anderson, MD, FAACR, is the Kraft Family Professor of Medicine at Harvard Medical School as well as Director of the LeBow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center at Dana-Farber Cancer Institute. He is a Doris Duke Distinguished Clinical Research Scientist, American Cancer Society Clinical Research Professor, and serves as Chair of the AACR Regulatory Science and Policy Subcommittee. After graduating from Johns Hopkins Medical School, he trained in internal medicine at Johns Hopkins Hospital, and then completed hematology, medical oncology, and tumor immunology training at the Dana-Farber Cancer Institute. Over the last four decades, he has focused his laboratory and clinical research studies on multiple myeloma. He has developed laboratory and animal models of the tumor in its microenvironment which have allowed for both identification of novel targets and validation of novel targeted therapies, and has then rapidly translated these studies to clinical trials culminating in FDA approval of novel targeted and immune therapies. His paradigm for identifying and validating targets in the tumor cell and its milieu has transformed myeloma therapy and markedly improved patient outcome.

Nicole Gormley, MD, *U.S. Food and Drug Administration, Moderator of Session 5*

Nicole Gormley, MD, is the Division Director for the Division of Hematologic Malignancies II at the U.S. Food and Drug Administration and serves as the Acting Associate Director for Oncology Endpoint Development in the Oncology Center of Excellence. The Division of Hematologic Malignancies II oversees the drug development of products for the treatment of multiple myeloma, lymphomas, and chronic lymphocytic leukemia. In her role as the Acting Associate Director of Oncology Endpoint Development, Dr. Gormley provides direction, coordination and oversight for scientific and policy efforts related to early endpoint development in oncology.

Dr. Gormley joined the FDA in 2011 and previously served as a clinical reviewer and the Multiple Myeloma Clinical Team Lead. While in these roles, Dr. Gormley actively engaged with the multiple myeloma community on the development of novel endpoints, including minimal residual disease, and methods to address racial disparities. Dr. Gormley completed fellowship training in hematology and critical care at the National Institutes of Health and served as the Deputy Clinical Director at the National Heart, Lung and Blood Institute prior to joining the Food and Drug Administration.

Ruixiao Lu, PhD, *Alumis Inc. & American Statistical Association, Moderator of Session 4*

Ruixiao Lu, PhD, is currently the Treasurer and Executive Committee Member of the Board of the American Statistical Association (ASA). She has held leadership positions at the ASA throughout the years, including Vice Chair of Council of Chapter Governing Board and San Francisco Bay Area Chapter President. She is dedicated in promoting cross-disciplinary partnerships, especially between the medical community and statistical/quantitative science community. For her day job, Dr. Lu is a Biometrics leader in the biotech/biopharma industry. She has served as functional head overseeing Biostatistics, Statistical Programming, and Clinical Data Management teams.

Dr. Lu's oncology experience is mostly in solid tumors including Breast Cancer and Prostate Cancer, with a special interest in biomarkers for targeted therapies and patient management. She was VP, Head of Statistics, Clinical Data Management & Data Science, overseeing the statistics and data analytical functions, at Quantum Leap Healthcare (QLHC), the trial sponsor of the I-SPY trials including the I-SPY 2 Breast Cancer Trial, which is among the first master protocol trials in Oncology. Before then, she was the Director of Clinical Biostatistics at Genomic Health/Exact Sciences, overseeing the function to develop complex prognostic and predictive genomic markers for personalized cancer diagnostics and management. Most recently, she ventured into the immunology field, and is currently VP, Head of Biostatistics & Statistical Programming, at Alumis Inc., a precision medicine company.

Lisa Rodriguez, PhD, *U.S. Food and Drug Administration, Moderator of Session 2*

Lisa R. Rodriguez, PhD, is the Deputy Division Director of the Division of Biometrics IX, Office of Biostatistics, Center for Drug Evaluation and Research at FDA, supporting hematology products. She received her B.S. degree in Applied Mathematics from California State Polytechnic University, Pomona, CA, and received M.S. degrees in Biometry and Statistics from Cornell University in Ithaca, NY. She also obtained her Ph.D. degree in Statistics from Cornell University.

Prior to joining FDA in 2012, Dr. Rodriguez worked for several years in industry supporting a variety of therapeutic areas, in addition to a research/teaching position at the North Carolina State University Statistics Department and Bioinformatics Research Center. Her work at FDA has covered issues in oncology, hematology, meta-analyses, benefit-risk evaluations for regulatory decision making, stem cell products, evaluation of biomarker and PRO/COA endpoints, survival analyses, biosimilars and adaptive designs. She has also participated in several advisory committee preparations, from both industry and FDA perspectives. Dr. Rodriguez is currently co-leading the Benefit-Risk Assessment Planning (BRAP) Taskforce within the ASA Biopharmaceutical Section Safety Working Group and is part of several internal FDA scientific working groups.

Speakers and Panelists (Alphabetically by Last Name)

Anup Amatya, PhD, *U.S. Food and Drug Administration, Session 5*

Anup Amatya, PhD, is a Lead Mathematical Statistician in the Division of Biostatistics V. He is a member of various working groups and committees within the Office of Biostatistics and Oncology Center of Excellence at FDA. Prior to joining FDA, he served as an Associate Professor at the New Mexico State University. He received his PhD in Biostatistics from the University of Illinois at Chicago.

Cong Chen, PhD, FASA, *Merck, Session 5*
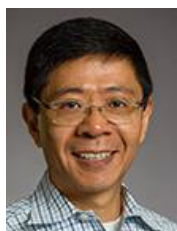
Cong Chen, PhD, FASA, is Scientific AVP in Early Development Statistics at Merck & Co., Inc., providing fit-for-purpose decision-making strategies and novel statistical approaches for early and early-to-late transitional oncology programs, and supporting oncology external collaborations, competitive intelligence, and high-profile due diligence projects. Prior to taking the role, he led the statistical support for the development of pembrolizumab and played a key role in accelerating its regulatory approvals.

He is an elected Fellow of American Statistical Association (2016), an Associate Editor of Statistics in Biopharmaceutical Research, a member of Cancer Clinical Research Editorial Board and a leader of the DIA Innovative Design Working Group. He has published over 100 papers and 10 book chapters on innovative design and analysis methods of clinical trials, has given multiple short courses on the subject at statistical conferences and was invited to give oral presentations at multiple medical conferences on design strategies for oncology drug development.

R. Angelo de Claro, MD, *U.S. Food and Drug Administration, Session 2*

R. Angelo de Claro, MD, is a hematology-oncology physician and currently the Associate Director (Acting) for Global Clinical Sciences with the Oncology Center of Excellence. In this role, he leads OCE efforts to advance cancer drug development and regulatory science across the globe, including direction of Project Orbis. Dr. de Claro is also the Division Director for the Division of Hematologic Malignancies I in the Office of Oncologic Diseases, Center for Drug Evaluation and Research, FDA.

George Demetri, MD, FAACR, *Dana-Farber Cancer Institute, Chair of Session 5*

George Demetri, MD, FAACR, received his AB in biochemical sciences from Harvard College and MD from Stanford University, then pursued internal medicine residency and Chief Residency at the University of Washington, Seattle and medical oncology fellowship at the Dana-Farber Cancer Institute and Harvard Medical School. He co-directs the Ludwig Center at Harvard to bring together more than 30 investigative teams to focus on understanding, overcoming, and preventing resistance to anticancer therapies. His career as a physician-scientist has focused on developing therapies targeting specific oncogenic mechanisms to treat precisely-defined subsets of sarcomas and other cancers. He was instrumental in the development of imatinib as the first effective therapy for gastrointestinal stromal tumor (GIST) as a paradigm of a mutation-driven solid tumor. His research efforts have subsequently contributed to FDA approval of multiple other therapies to treat GIST, other sarcomas as well as other malignancies. On the basis of this body of work, Dr. Demetri was awarded the 2020 David A. Karnofsky Memorial Award from the American Society of Clinical Oncology (ASCO). A former member of the Board of Directors of the American Association for Cancer Research (AACR), he is a member and immediate past Chair of the AACR Science Policy and Government Affairs Committee.

Laura J. Esserman, MD, MBA, FAACR, *University of California San Francisco, Session 2*

Laura Esserman, MD, MBA, FAACR, is Professor of Surgery and Radiology at the University of California, San Francisco (UCSF) and director of the UCSF Breast Care Clinic. Her work in breast cancer spans the spectrum from basic science to public policy issues, and the impact of both on the delivery of clinical care. Dr. Esserman is recognized as a thought leader in cancer screening and over-diagnosis, as well as innovative clinical trial design. She led the creation of the University of California-wide Athena Breast Health Network, a learning system designed to integrate clinical care and research as it follows 150,000 women from screening through treatment and outcomes. The Athena Network launched the PCORI-funded Wisdom Study, which tests a personalized approach to breast cancer screening in 100,000 women. She is also a leader of the innovative I-SPY TRIAL model, designed to accelerate the identification and approval of effective new agents for women with high risk breast cancers. In 2020, she got FDA approval for an I-SPY COVID trial, designed to rapidly screen and confirm high impact treatments to reduce mortality and time on ventilators.

Jaleh Fallah, MD, *U.S. Food and Drug Administration, Session 2*

Jaleh Fallah, MD, is a medical oncologist at the Division of Oncology 1 (DO1), Genitourinary Cancers, US Food & Drug Administration (FDA). Dr. Fallah received her MD from Isfahan University of Isfahan in Iran. She then moved to the United Stated, where she completed her Internal Medicine residency at Brown University and her Hematology and Oncology fellowship at Cleveland Clinic. Her clinical interests are GU malignancies, brain metastasis, and biomarkers. During her fellowship training, she wrote protocols for several clinical trials in bladder cancer and brain tumors. Upon completion of her fellowship training in 2020, she joined FDA as a clinical reviewer. During this time, she has evaluated trial designs as well as safety and efficacy of therapeutics in all stages of clinical development from pre-investigational new drugs through marketing approvals.

'Lola Fashoyin-Aje, MD, MPH, *U.S. Food and Drug Administration, Session 1*

Lola A. Fashoyin-Aje, MD, MPH, is a medical oncologist and Deputy Director in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Center for Drug Evaluation and Research-Food and Drug Administration (FDA). In this role, she provides clinical, scientific, and regulatory policy guidance and oversight to multidisciplinary teams reviewing drugs and biologics under development for the treatment of solid tumor malignancies. Dr. Fashoyin-Aje is also an Associate Director at the FDA Oncology Center of Excellence at the FDA, where she leads initiatives to address clinical and regulatory science and policy issues impacting oncology drug development. Prior to joining the FDA, Dr. Fashoyin-Aje completed her undergraduate and graduate training at Columbia University and Yale University, respectively, and received her MD degree from the University of Rochester School of Medicine and Dentistry. She completed postgraduate training in internal medicine and medical oncology at Johns Hopkins.

Keith Flaherty, MD, FAACR, *Massachusetts General Hospital Cancer Center, Chair of Session 4*

Keith Flaherty, MD, FAACR, is Director of Clinical Research at the Massachusetts General Hospital Cancer Center, and Professor of Medicine at Harvard Medical School. As described in the more than 300 peer reviewed primary research reports he has authored or co-authored, Dr. Flaherty and colleagues made several seminal observations that have defined the treatment of melanoma when they established the efficacy of BRAF, MEK and combined BRAF/MEK inhibition in patients with metastatic melanoma in a series of New England Journal of Medicine articles for which Dr. Flaherty was the first or senior author. He is the principal investigator of the NCI MATCH trial, the first NCI-sponsored trial assigning patients to targeted therapy independent of tumor type on the basis of DNA sequencing detection of oncogenes. Dr. Flaherty joined the NCI Board of Scientific Advisors in 2018 and AACR Board of Directors in 2019. He serves as editor-in-chief of *Clinical Cancer Research*. Dr. Flaherty co-founded Loxo Oncology in 2013 and served on the board of directors through the acquisition by Eli Lilly in 2019. He co-founded X4 Pharmaceuticals (NASDAQ: XFOR) and privately held Strata Oncology (2015), Apricity Oncology (2017), C-Reveal (2020), and most recently, Scorpion Therapeutics (2020). He serves on the boards of directors for Clovis Oncology and Kinnate BioPharma, along with Strata Oncology and Scorpion Therapeutics.

Boris Freidlin, PhD, *National Cancer Institute, Session 2*

Boris Freidlin, PhD is chief of the Biostatistics Branch, in the Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI). He has been with the NCI since 1998. His research interests include design and analysis of adaptive clinical trials and methodologies for evaluation of new cancer treatments and companion biomarkers. Dr. Freidlin serves on the NCI Myeloma, Lymphoma, Leukemia Steering Committees and on the NCI Pediatric Leukemia & Lymphoma and Pediatric Solid Tumor Steering Committees. Prior to joining the NCI, he worked for the Emmes Corporation and the George Washington University Biostatistics Center. Dr. Freidlin holds a BS degree in mathematics from the University of Maryland and a PhD degree in statistics from the George Washington University.

Cindy Gao, PhD, *U.S. Food and Drug Administration, Session 2*

Xin "Cindy" Gao, PhD, is a Mathematical Statistician at CDER in FDA. She earned a PhD in Biostatistics from the Department of Biostatistics at 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 with external control, surrogacy evaluation and missing data analysis etc. which led to publications in statistical and clinical oncology journals such as statistics in medicine and clinical cancer research.

Elizabeth Garrett-Mayer, PhD, *American Society of Clinical Oncology, Session 4*

Elizabeth Garrett-Mayer, PhD, joined ASCO in 2017 as CENTRA's Division Director for Biostatistics and Research Data Governance and became CENTRA's first Vice President in 2022. CENTRA leads ASCO's research efforts, including the TAPUR Study, ASCO's COVID-19 Registry, and research projects aimed at dose optimization and increasing minority enrollment in clinical trials. Prior to joining ASCO, she served on the faculty in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in the Department of Oncology, and then joined the faculty of the Medical University of South Carolina (MUSC) and established the Biostatistics Shared Resource at the Hollings Cancer Center (HCC).

She earned her bachelor's degree from Bowdoin College and a PhD in Biostatistics from Johns Hopkins Bloomberg School of Public Health. During her time at Johns Hopkins and MUSC, she taught courses in biostatistics and public health science, and mentored pre- and post-doctoral students. Her publication record includes more than 300 peer-reviewed publications, primarily in early phase clinical trial design methods and clinical cancer research. She has been a member of numerous NIH grant review committees, NCI task forces and steering groups, Data Safety Monitoring Boards for NIH-supported clinical trials, serves on the editorial board of three peer-reviewed journals and was faculty on the ASCO/AACR Methods in Clinical Cancer Research Workshop for over a decade.

Marjorie C. Green, MD, *Merck, Session 4*

Marjorie C. Green, MD, is a Senior Vice President who leads the Late-Stage Clinical Development Oncology Team at Merck Research Laboratories. Dr. Green has more than 20 years of experience in oncology clinical trials including her experience as a clinical investigator and in pharma drug development. Prior to joining Merck, Marjorie was senior vice president and head of late-stage oncology at Seagen, leading clinical development of a diverse portfolio of oncology candidates including multiple antibody drug conjugates. Prior to joining Seagen, she held positions of increasing responsibility at Genentech culminating in her tenure as vice president, Global Product Development, head of breast and gynecologic tumor franchise. Previously, she was assistant professor and medical director of the Nellie B. Connally Breast Center and vice-chair of the Institutional Review Board at the MD Anderson Cancer Center, Houston, Texas. During her tenue at MD Anderson, Marjorie established herself as a nationally recognized clinical expert in the management of breast cancer and the treatment and prevention of associated bone metastases and has authored multiple manuscripts and book chapters on preoperative chemotherapy. Marjorie received her Bachelor of Arts from the University of Notre Dame and her medical degree from the University of Texas Medical Branch. She conducted an internal medicine residency at University of Virginia School of Medicine and completed fellowships in medical oncology and hematology at the MD Anderson Cancer Center.

Wenjuan Gu, PhD, *U.S. Food and Drug Administration, Session 3*

Wenjuan Gu, PhD, is a senior mathematical statistician in the Division of Biometric IX in the Office of Biostatistics in the Center for Drug Evaluation and Research (CDER), which supports the pre-market reviews and approvals in the Division of Hematologic Malignancies II, Office of Oncologic Diseases. She is a statistics representative for the Oncology Center of Excellence (OCE) Pediatric Review Committee subcommittee.

Roy S. Herbst, MD, PhD, *Yale Cancer Center, Session 1*

Roy S. Herbst, MD, PhD, serves as the Ensign Professor of Medicine and Professor of Pharmacology; Deputy Director; Chief of Medical Oncology; Assistant Dean for Translational Research; and Director, Center for Thoracic Cancers at Yale Cancer Center and Yale School of Medicine.

Dr. Herbst is a pioneer of personalized medicine and immunotherapy to identify biomarkers and bring novel targeted treatments to patients, serving as principal investigator for trials leading to approval of several therapies revolutionizing the field. He has authored more than 450 publications. The NCI Lung SPORE he leads has identified new mechanisms of sensitivity and resistance to immunotherapy. His work on Lung MAP, has galvanized the field by developing public-private partnerships to conduct large clinical studies. For his lifetime achievement in scientific contributions to thoracic cancer research, Dr. Herbst was awarded the 2016 Paul A. Bunn, Jr. Scientific Award by IASLC. A team of Yale Cancer Center investigators led by Dr. Herbst was awarded the 2018 Team Science Award from the Association for Clinical and Translational Science for its pioneering work in advancing our understanding of Immunotherapy. In 2020, Dr. Herbst was awarded the AACR Distinguished Public Service Award for Exceptional Leadership in Cancer Science Policy.

Dr. Herbst serves as Chair of the AACR Scientific Policy and Government Affairs Committee. He has been a major proponent of efforts to promote tobacco control and regulation (including e-cigarettes), authoring multiple policy statements and leading frequent Capitol Hill briefings. In 2019, he was elected to the IASLC board of directors and the board of directors of AACR. He is a fellow of the American College of Physicians, American Society of Clinical Oncology, and an elected member of the Association of American Physicians.

Alexei C. Ionan, PhD, *U.S. Food and Drug Administration, Session 1*

Alexei C. Ionan, PhD, is a Mathematical Statistician in the Division of Biometrics IX of the Office of Biostatistics, supporting application review in the Office of Oncologic Diseases at the FDA. He has been evaluating, developing, and applying statistical methods in oncology since 2003. He leads multiple groups at the FDA. His research interests include Bayesian methods, estimands, decision theory, causal inference, predictive biomarkers, early detection of cancer, and optimal design.

Bindu Kanapuru, MD, *U.S. Food and Drug Administration, Session 3*

Bindu Kanapuru, MD, is a board-certified hematologist-oncologist and the Multiple Myeloma Team Lead in the Division of Hematologic Malignancies 2 (DHM2) in the Office of Oncologic Diseases (OOD). She also serves as a Cross Center Team Lead for Multiple Myeloma at the US Food and Drug Administration. Dr. Kanapuru joined the FDA in 2015. Her areas of interest include disparities in clinical trials and novel trial designs. She serves as the scientific liaison for geriatric hematologic malignancies. Dr. Kanapuru completed her fellowship in hematology and oncology at the University of Maryland Medical Center in Baltimore. During her fellowship she did her research at the National Institute on Aging on mechanisms of unexplained anemia and cancer in older adults, and co-authored book chapters and publications.

Margret Merino, MD, *U.S. Food and Drug Administration, Session 1*

Margret Merino, MD, is a medical officer on the lymphoma team in the Division of Hematologic Malignancies 2 (DHM2), in the Center for Drug Evaluation and Research (CDER) of the United States Food and Drug Administration (FDA). She joined FDA in 2016 and serves on the lymphoma team where her duties include IND and marketing approvals for products in development for hematologic malignancies. She has authored manuscripts presenting summaries of FDA drug approvals and summarizing discordant early endpoint and OS results in oncology trials. Dr. Merino received her medical degree from New York Medical College in Valhalla, NY and completed a pediatric residency and pediatric hematology-oncology fellowship at the Walter Reed Army Medical Center and Uniformed Services University of the Health Sciences. Her fellowship research was completed at the NCI and focused on detection of minimal residual disease in patients with Ewing sarcoma. Prior to joining the FDA, Dr. Merino was a medical officer in the United States Army, serving as a pediatric hematologist oncologist at the Walter Reed National Military Medical Center and Tripler Army Medical Center. At Walter Reed, she served as director the pediatric hematology-oncology fellowship program, was a member of the Children's Oncology Group (COG). Her interests include endpoints in lymphoid malignancies, pediatric lymphoma, late effects and survivorship.

Ruben Mesa, MD, *Atrium Health, Chair of Session 2*

Ruben Mesa, MD, FACP recently began his tenure leading the mission and programs against cancer across Atrium Health and Atrium Health Wake Forest Baptist with the joint roles of President, Levine Cancer Institute; Enterprise Senior Vice President, Atrium Health; Executive Director, Atrium Health Wake Forest Baptist Comprehensive Cancer Center; and Vice Dean for cancer programs at Wake Forest School of Medicine. In these roles Dr. Mesa oversees all efforts related to cancer practice, research and education across Atrium Health as a system including Wake Forest Baptist, Levine Cancer Institute, and all regional sites. Dr. Mesa previously was the Executive Director of the NCI Designated Mays Cancer Center at UT Health San Antonio MD Anderson from 2017-2023 where he developed and grew the cancer service line, co-led the development and construction of a new cancer focused hospital, grew cancer faculty, peer reviewed funded research and successful renewed the NCI designation in 2020. Earlier in his career Dr Mesa practiced hematology at Mayo Clinic (MN 2002-2009, and Arizona (2009-2017)) where he was Chair of Hematology & Medical Oncology and Deputy Director of the Mayo Clinic Comprehensive Cancer Center.

Dr Mesa, is an international expert in hematologic cancers, who has dedicated his life's work to research and drug development for myeloproliferative neoplasms (MPNs). Dr. Mesa is a funded investigator of the NCI on several projects in MPNs and has been appointed to the NCI Clinical Trial Advisory Committee. He plays a range of leadership roles with

the American Society of Hematology, the American Association of Cancer Research, and is currently elected to the Board of the American Association of Cancer Institutes and an executive officer of the board for the Leukemia and Lymphoma Society. Dr. Mesa has won many career awards for his research from Mayo Clinic, from patient and MPN organizations.

Pallavi Mishra Kalyani, PhD, *U.S. Food and Drug Administration, Session 5*

Pallavi Mishra-Kalyani, PhD, is a Supervisory Mathematical Statistician in the Division of Biometrics V, Office of Biostatistics which supports Office of Oncology Drugs at the Center for Drug Evaluation and Research (CDER). Since joining the FDA in 2015, Dr. Mishra-Kalyani has contributed to the efforts to understand and address the statistical issues related to the potential use of external controls, 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 organized and participated at several statistics and oncology workshops, conferences, and working groups on these topics. Dr. Mishra-Kalyani received her doctorate in Biostatistics from Emory University, her Master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University, and her Bachelor's degree from MIT.

David Mitchell, *Patients for Affordable Drugs, Session 5*
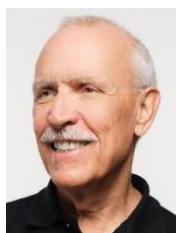
David Mitchell is a patient with an incurable — but treatable — blood cancer called multiple myeloma. He depends on drugs costing hundreds of thousands of dollars a year for his survival, and expects to be in continuous treatment until he dies. Myeloma is smart and finds its way around drugs, so David is a strong supporter of innovation and new drugs to extend his life, and the lives of other patients. But he adamantly believes drugs don't work if people can't afford them. The Washingtonian called David "an integral player in forcing the prescription-drug provision into the Inflation Reduction Act." STAT News reported, "Mitchell has filled an important void as a politically savvy patient advocate who was well-funded but didn't take a penny from the pharmaceutical industry." David has more than 40 years of experience working on health care and public health policy as a communications specialist. He helped build and run for more than 30 years GMMB — a cause-oriented, public policy communications firm in Washington, DC. There he worked to reduce teen smoking, increase use of seat belts, fight drunk driving and improve child health and safety. He retired in 2016 to focus his full energy and attention on helping bring about policy change to lower prescription drug costs, launching Patients For Affordable Drugs in February, 2017. David also serves as a consumer representative on the FDA Oncologic Drugs Advisory Committee.

Pabak Mukhopadhyay, PhD, *AstraZeneca, Session 1*

Pabak Mukhopadhyay, PhD, heads the breast cancer biometrics group at AstraZeneca, responsible for overseeing the entire late stage BC portfolio at AZ. Prior to AZ, he worked at Novartis, Schering-Plough and Daiichi-Sankyo and has 23 plus years of drug development experience, spanning multiple therapeutic areas, including cardio vascular diseases, inflammatory diseases, HCV and Oncology. Dr Mukhopadhyay has been working in the breast cancer field for the last 15 years and has led biometrics teams through development and global regulatory approvals of several key products including Afinitor, Kisqali, Enhertu, Alpelisib among others. Dr. Mukhopadhyay obtained his Ph.D. in Statistics from North Carolina State University. He is passionate about drug development and in particular using novel statistical approaches to accelerate drug development including use of adaptive and interim analysis.

Grzegorz S. Nowakowski, MD, *Mayo Clinic, Sessions 3 & 5*

Grzegorz "Greg" Nowakowski, MD, FASCO, is a consultant and a Professor of Medicine and Oncology, Division of Hematology at Mayo Clinic in Rochester, Minnesota where he also serves as the Enterprise Deputy Director of Mayo Clinic Comprehensive Cancer Center for Clinical Research, the Chair of Lymphoid Malignancy Group, and the vice-Chair of Division of Hematology. Dr. Nowakowski is an international expert in hematological malignancies. Dr. Nowakowski's research focuses on new approaches to clinical trial design and novel therapies for lymphoma. He serves as a principal investigator of multiple investigator-initiated and cooperative group clinical trials (ECOG, Alliance) and industry sponsored studies and currently serves and a member of ECOG Lymphoma Core Committee. Dr. Nowakowski chairs the Lymphoma Committee and Hematological Malignancy Program in the Academic and Community Cancer Research United (ACCRU) network. He currently serves as the chair of ASH Clinical Trial Innovation Subcommittee and the chair of ASCO Clinical Trial Access and Participation Taskforce. Dr. Nowakowski has significant regulatory experience, both serving as a PI of regulatory studies and working with regulatory agencies, including his service as a Voting Member of the Oncology Drugs Advisory Committee (ODAC) to the Food and Drug Administration (FDA). Dr. Nowakowski has authored over 250 articles and numerous book chapters and mentored many faculty members in US and abroad.

Richard Pazdur, MD, *U.S. Food and Drug Administration*

Richard Pazdur, MD, is director of FDA's Oncology Center of Excellence (OCE), which leverages the combined skills of FDA's regulatory scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel cancer products. In this role, Dr. Pazdur leads the effort to develop and execute an integrated regulatory approach to enhance cross-center coordination of oncology product clinical review.

Prior to joining FDA in 1999, Dr. Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center. From 1982 to 1988, he served on the faculty of Wayne State University. He received his bachelor's degree from Northwestern University, his M.D. from Loyola Stritch School of Medicine, and completed clinical training at Rush-Presbyterian St. Luke's Medical Center and University of Chicago Hospitals and Clinics.

Dr. Pazdur has published more than 800 articles, book chapters, and abstracts, and two medical oncology textbooks. He was recognized in Fortune's 2015 list of "50 World's Greatest Leaders." In 2016, he was named to Massachusetts General Hospital Cancer Center's "The One Hundred" list. In 2017, he was chosen as one of "The Bloomberg 50." In 2019, he was named one of OncLive's "Giants of Cancer Care." He has received numerous awards from professional societies including the American Society of Clinical Oncology, American Association for Cancer Research, National Coalition for Cancer Survivorship, LUNGevity Foundation, American Society for Clinical Pharmacology and Therapeutics, National Organization for Rare Disorders, Reagan-Udall Foundation for the FDA, the FDA Alumni Association, University of Chicago Cancer Research Foundation, and the Regulatory Affairs Professionals Society.

Tatiana M. Prowell, MD, *U.S. Food and Drug Administration, Session 1*

Tatiana M. Prowell, MD, is a medical officer and Breast Cancer Scientific Liaison at the U.S. Food and Drug Administration and an Associate Professor of Oncology in the Women's Malignancies Disease Group at the Johns Hopkins Kimmel Comprehensive Cancer Center. She was a key contributor to FDA's policy on accelerated approval using pathological complete response as a novel regulatory endpoint in the neoadjuvant high-risk breast cancer setting and a member of the Biden Cancer Moonshot Blue Ribbon Panel Cancer Immunology Working Group. She is a three-time recipient of FDA's Excellence in Communication Award, the 2018 Merrill Egorin Mentorship Award, the 2019 John and Samuel Bard Medal in Science or Medicine, the 2020 Webby Special Achievement Award for use of social media during the pandemic, and a past Giants of Cancer Care Award finalist. A passionate medical educator and mentor, she has served as Chair of the 2020 ASCO Annual Meeting Education Committee and as faculty in the ASCO/AACR Vail Methods in Clinical Cancer Research Workshop, the Society for Translational Oncology Fellows' Forum, and the FDA-ASCO Fellows' Day Workshop. She practices in the second opinion breast cancer clinic at the Johns Hopkins, where she also teaches in the medical school and the medical oncology fellowship training program. Dr. Prowell received her BA degree from Bard College in Languages and Literature and her MD degree from the Johns Hopkins University School of Medicine with election to the Phi Beta Kappa and Alpha Omega Alpha academic honor societies. She completed her residency and fellowship training at Johns Hopkins Hospital.

Mary W. Redman, PhD, *Fred Hutchinson Cancer Center, Session 4*

Mary W. Redman, PhD, is a Professor in Clinical Biostatistics in the Clinical Research Division at Fred Hutchinson Cancer Center. She has extensive experience in clinical trials, in particular, in phase II and III trials incorporating biomarkers particularly in lung cancer. Dr. Redman is the Statistical Chair for the Lung Cancer Committee in the SWOG Cancer Research Network, the head of the Biostatistics Core for the Fred Hutch Lung SPORE, and the Statistical Chair for the Lung-MAP Master Protocol, the first of the master protocols launched within the National Clinical Trials Network, and a trial that has served as a model for master protocols and the FDA guidance on master protocols.

Nicholas Richardson, DO, MPH, *U.S. Food and Drug Administration, Session 5*

Nicholas Richardson, DO, MPH, serves as a Clinical Team Leader for lymphoma at FDA. Dr. Richardson completed a clinical fellowship in pediatric hematology and oncology at the Monroe Carell Jr. Children's Hospital at Vanderbilt and a residency at the DuPont Hospital for Children in Wilmington, DE. Dr. Richardson earned a DO degree from the Philadelphia College of Osteopathic Medicine and an MPH from Vanderbilt.

Mikkael A. Sekeres, MD, MS, *Sylvester Comprehensive Cancer Center, University of Miami, Chair of Session 1*

Mikkael A. Sekeres, MD, MS, is Professor of Medicine with Tenure and Chief of the Division of Hematology at the Sylvester Comprehensive Cancer Center, University of Miami Miller School of Medicine. He earned a medical degree and a master's degree in clinical epidemiology from the University of Pennsylvania School of Medicine. Dr Sekeres completed his postgraduate training at Harvard University, finishing an internal medicine residency at Massachusetts General Hospital and a fellowship in hematology-oncology at the Dana-Farber Cancer Institute in Boston. He is chair of the medical advisory board of the Aplastic Anemia and Myelodysplastic Syndrome (MDS) International Foundation, and formerly chaired the FDA Oncologic Drugs Advisory Committee.

Dr. Sekeres is a member of the American Society of Hematology, where he serves on the Executive Committee and chairs the Committee on Communications. His research focuses on patients with MDS and older adults with acute myeloid leukemia, and he has been the national and international primary study investigator on dozens of phase I/II/III trials. He is the author or co-author of over 450 manuscripts and 650 abstracts. He was the inaugural editor-in-chief of the ASH Clinical News magazine; he is on the editorial board of several journals; has written 100 essays for The New York Times, The Washington Post, Huffington Post, Slate, and The Hill, among others; and has authored 8 books, including When Blood Breaks Down: Life Lessons from Leukemia (The MIT Press 2020) and Drugs and the FDA: Safety, Efficacy, and the Public's Trust (The MIT Press 2022).

Michael Shan, PhD, *Bayer, Session 2*

Minghua "Michael" Shan, PhD, is a Senior Director, Expert Statistician at Bayer U.S. LLC, Pharmaceuticals, and a Bayer Science Fellow. He has 29 years of extensive experience in clinical trials, primarily specializing in oncology. Over the past more than two decades, he has dedicated his efforts to supporting the development of oncology drugs, contributing to the design, conduct, and analysis of numerous clinical trials in this field. His expertise encompasses all phases of clinical investigations, from early stages to obtaining regulatory approvals. He holds a doctorate degree in Statistics from the University Kentucky and is a member of American Society of Clinical Oncology.

Qian Shi, PhD, *Mayo Clinic, Session 3*

Qian Shi, PhD, is a Consultant in Quantitative Science, Professor of Biostatistics and Oncology at Mayo Clinic and Mayo College of Medicine, in Rochester, MN. She oversees statistical teams in Gastrointestinal (GI) Cancer research committees in Mayo Clinic Cancer Center as well as Alliance for Clinical Trials in Oncology. In addition, Dr. Shi serves as the Director of the Biostatistics Shared Resource at Mayo Clinic Cancer Center. Dr. Shi has been leading 7 large international databases research, and the Primary Investigator (PI), Co-PI, Co-Investigator on many NCI grants, as well as research funded by industry and foundations.

Dr. Shi's research is focused on statistical methodological research in surrogate endpoint evaluations in clinical trials, hierarchical Bayesian clinical trial design, biomarker-driven trial design, and international large database sharing and research initiatives. Dr. Shi has been collaborating extensively with oncologists, surgeons, radiologists, pathologists, basic science researchers on medical research projects, especially clinical trials in GI cancers. Dr. Shi has served as the primary

statistician on > 20 Phase II or Phase III oncology clinical trials conducted nationally and internationally, sponsored by NCI and industry. Shi has served on Evidence-Based Medicine Core Team and Lower Gastrointestinal Tract Expert Panel of American Joint Committee on Cancer (AJCC), NCI Gastrointestinal Steering Committee (GISC) and Taskforces, NIH Cancer Prevention Study Section, multiple Mayo Clinic institutional and external industry Data and Safety Monitoring Boards.

Harpreet Singh, MD, *U.S. Food and Drug Administration, Session 4*

Harpreet Singh, MD, is director of the Division of Oncology 2 in the Office of Oncology Diseases, as well as the Associate Director for Cancer in Older Adults and Special Populations in the Oncology Center of at the FDA. Dr. Singh is originally from Los Angeles, and received her MD degree from the University of Southern California. She completed her Internal Medicine residency and Geriatrics fellowship at USC, followed by a Medical Oncology fellowship at the National Cancer Institute. While at USC she was mentored by Dr. Anthony EL-Khoueiry and worked with the Lenz lab on translational projects addressing the role of KRAS and EGFR in metastatic colon cancer.

As Director of the Division of Oncology 2 at the FDA, Dr. Singh oversees drug development for lung cancer, head and neck cancer, neurologic tumors, pediatric solid tumors, and several cancers. Her scope of expertise includes precision medicine and targeted therapy, novel trial design, innovative regulatory initiatives designed to expedite drug approvals, and pragmatic trials.

In her role as Associate Director for Cancer in Older Adults, Dr. Singh leads multiple OCE efforts to advance drug development and regulatory science for older adults with cancer and special populations. Dr. Singh has expertly engaged with the greater scientific community, to increase the evidence base for treating older adults with cancer. She has consistently presented her FDA research on this topic at major academic conferences and published in peer reviewed journals such as the New England Journal of Medicine, Journal of Clinical Oncology, JAMA Oncology, etc.

Steven Snapinn, PhD, FASA, *Seattle-Quilcene Biostatistics, LLC, Chair of Session 3*

Steven Snapinn, PhD, FASA, 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.

Dr. Snapinn received a PhD in Biostatistics from the University of North Carolina before entering the pharmaceutical industry. While at Merck he led the biostatistical efforts for multiple landmark cardiovascular outcomes trials, and while at Amgen he oversaw the biostatistical work for over a dozen successful pharmaceutical products in multiple therapeutic areas. In 2019, Dr. Snapinn formed a biostatistical consulting company, Seattle-Quilcene Biostatistics LLC.

Dr. Snapinn has over 100 publications in the statistical and medical literature. He is a fellow of the American Statistical Association, has served as editor of the journal Statistics in Biopharmaceutical Research and as Associate Editor for multiple journals, and is currently the chair of the ASA's Committee on Publications.

## Craig Tendler, MD, *Janssen of Johnson & Johnson, Session 5*

Craig Tendler, MD, is Vice President and Global Head of Clinical Development, Diagnostics, and Medical Affairs for the Oncology Therapeutic Area at Janssen Research & Development, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. In this position, he is responsible for creating and overseeing robust development plans, including optimal integration of biomarkers and diagnostics, and comprehensive data generation activities for all products in the oncology portfolio, from proof of concept through registration and lifecycle management. He works closely with teams in early development and the disease areas of focus to implement a seamless end-to-end oncology clinical research strategy that incorporates compelling science, broad clinical trial access to diverse populations, and addresses areas of high unmet medical need.

Craig has overseen and coordinated more than 30 major drug approvals by national regulatory agencies, including at least ten NDAs by FDA. He and his have team worked in collaboration with the FDA and the European Medicines Agency to secure the worldwide approvals of Janssen's treatments in prostate cancer, hematologic malignancies, as well as for lung and bladder cancer. Further, together with his team, Craig has been instrumental in achieving 11 FDA breakthrough designations of promising investigational medicines intended for the treatment of serious oncology conditions.

Prior to joining Janssen, Craig served as the Vice President of Oncology Clinical Research and Chair of the Oncology Licensing Committee at the Schering-Plough Research Institute. He also served as Assistant Professor of Pediatrics/Hematology-Oncology at the Mount Sinai School of Medicine in New York City and as a research fellow at the NCI in Bethesda, MD. Craig earned his undergraduate degree from Cornell University, and graduated from the Mount Sinai School of Medicine, New York City, with high honors and induction into the Alpha Omega Alpha Medical Society.

Jonathon Vallejo, PhD, *U.S. Food and Drug Administration, Moderator of Session 3*
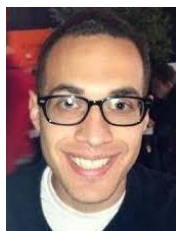
Jonathan Vallejo, PhD, is a supervisory statistician in the Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. He earned his PhD in statistics from Baylor University.

Paz Vellanki, MD, PhD, *U.S. Food and Drug Administration, Session 3*

Paz Vellanki, MD, PhD, is a medical oncologist and cross-disciplinary team leader on the thoracic and head and neck cancer team at the U.S. Food and Drug Administration (FDA). In this role, she focuses on the regulation of drugs and drug approvals for patients with lung and head and neck cancers. She continues to care for patients with head and neck cancer as a Clinical Assistant Professor at the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center.

Prior to working at the FDA, she received her MD/PhD at the University of Maryland, School of Medicine. Her doctoral work was in Biochemistry and involved studying the structural and molecular biology of MutY Homolog, a DNA repair enzyme mutated in a hereditary colorectal cancer syndrome. She completed her residency in Internal Medicine at the Wake Forest, School of Medicine in Winston-Salem, North Carolina and her fellowship in Oncology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in Baltimore, Maryland.

Qi Xia, PhD, *Abbvie, Session 2*
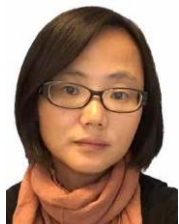
Qi Xia, PhD, is the Head of Statistics, Oncology, at Abbvie. She joined Abbvie in 2021, providing strategic, operational, and technical guidance for all statistical deliverables within the oncology therapeutic area, from first-in-human studies to regulatory approvals. Prior to that she was a Senior Director at Genentech/Roche, overseeing the data sciences and statistics group in the late-stage development of a number of molecules across different disease indications and development stages. She received her PhD in Statistics from Rutgers University. Dr. Xia is passionate about rigorous drug development, innovative trial design, and robust decision making. She is particularly interested in improving drug development via practical innovation and increased efficiency.

## Jianjin Xu, PhD, *U.S. Food and Drug Administration, Session 4*
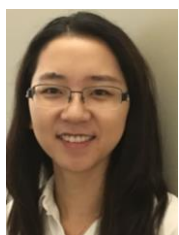
Jianjin Xu, PhD, is a statistical reviewer from DBV/CDER/FDA. She got a PhD degree in Applied Mathematics and Statistics from Stony Brook University in 2017. She started her career in the biostatistics division at CDRH in 2017 and then joined her current division at CDER in 2021. Her team is responsible of reviewing regulatory submissions for breast, gynecologic, and genitourinary cancers.

Qing Xu, PhD, *U.S. Food and Drug Administration, Session 3*
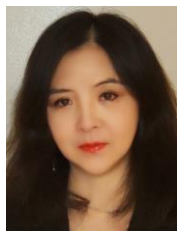
Qing Xu is a statistical team leader at the FDA, specializing in cancer products. With over 15 years of experience in the field, she has emerged as a leading expert in oncology and has played a pivotal role in helping regulatory decisions for oncology products. She has also led and participated in various regulatory research working groups, contributing to the development of guidance documents. Dr. Xu holds a PhD degree in Biostatistics from the University of Pittsburgh.

Anas Younes, MD, *AstraZeneca, Session 1*
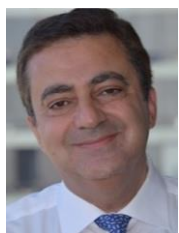
Anas Younes, MD, is the Senior Vice President, Global Head of Hematology (Early and Late Stage) Oncology R&D at AstraZeneca with responsibilities spanning from early discoveries and target identification, to first-in-human clinical studies, to late stage trials and drug approvals. Dr. Younes is clinician-scientist and has spent more than 25 years caring for patients with lymphoma. Prior to joining AstraZeneca, he was at Memorial Sloan Kettering Cancer Center (MSKCC) where he served as the Chief of the Lymphoma Service, in addition to leading a laboratory focused on drug development for patients with lymphoid malignancies. His lab was focused on accelerating the translation of scientific discoveries into novel treatment strategies to improve the cure rate and survival of patients with Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). Prior to MSKCC, He worked for 20 years at University of Texas MD Anderson Cancer Center (MDACC) where he directed clinical and translational research in the Department of Lymphoma and Myeloma.

Godwin Yung, PhD, *Genentech/Roche, Session 1*

Godwin Yung, PhD, is a statistician in the statistical Methods, Collaboration, and Outreach (MCO) group at Genentech/Roche. As such, he collaborates with colleagues to ensure that the most appropriate quantitative methodologies are used in pharmaceutical development, and networks with statisticians outside of the company to move the field of statistics and public health forward. Relevant to this workshop, Dr. Yung has conducted research on the topic of randomization in survival studies. He is also an active member of the cross-industry oncology estimands working group. Dr. Yung received his PhD in Biostatistics from Harvard University.

Jian Zhao, PhD, *U.S. Food and Drug Administration, Session 2*

Jian Zhao, PhD, is a Mathematical Statistician at FDA. Prior to joining FDA, Dr. Zhao served as a biostatistician in private industry at MacroGenics, PPD, Inc., the EMMES Corporation, and Frontier Science and Technology Research Foundation. Dr. Zhao earned a PhD in Statistics from the University of Maryland Baltimore County and a Master's degree from the University of Illinois Chicago.

Emmanuel Zuber, PhD, *Novartis Pharma AG, Session 3*

Emmanuel Zuber, PhD, has been working as a statistician in global drug development for more than 25 years, with over 21 years dedicated to Oncology and Hematology indications, in several large pharmaceutical companies. Through a variety of leadership roles, he has been directly involved in or has overseen over a dozen of successful global developments, filings and approvals, of treatments of different kinds (cytotoxic chemotherapies, targeted therapies, cell therapies, biologics, or radio-ligand therapies).

Dr Zuber has been with Novartis (Basel, Switzerland) since 2004. As a Vice President for the last 12 years, he has led teams and organizations of different sizes. His passion has been to develop their innovative capability, their scientific, strategic and operational excellence, and their external and internal collaborative leadership.

His keen interest in an open dialogue between drug developers and regulators, to enable evidence based and efficient drug development paths, has led Dr Zuber to be an organizing and scientific committee member of the yearly Regulatory Statistics Workshop of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) since its first occurrence in 2016.

He holds a PhD in biostatistics from the University of Lyon I, France, and a Master in life sciences engineering from the Institut National des Sciences Appliquées (INSA), Lyon, France.